ESCHWEILER combi line

Blood-Gas-Electrolyte-Metabolite Analyser

For In-Vitro-Diagnostic Use

Instruction Manual

IVD

CE

Eschweiler GmbH & Co. KG

Development - Manufacturing - Sales - Technical Service

Made in Germany

Instruction Manual

Manual Version

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Manual History

Manual Version	ANALYSER-Software Version	Revision Date
4.01	2500	April 2010

Software Copyrights

The software for the combi*line* Analyser is the User and Instrument Control Software for the combi*line*. The combi*line* Software is the intellectual property of Eschweiler GmbH & Co. KG hereafter Eschweiler. Intellectual property rights shall remain with Eschweiler.

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E-Mail: info@eschweiler-kiel.de

Consumable solutions and spare parts from other manufacturers used in ESCHWEILER Analysers.

We point out specifically that fault-free operation of our analysers can be guaranteed only when original **ESCHWEILER** solutions and spare parts are used.

The name **ESCHWEILER** with its decades of experience in the field of blood gas analysis also stands for the quality of the spare parts and consumable solutions. **ESCHWEILER** sensors and solutions form a functional unit whose components are optimally adapted to each other. Measuring accuracy and long life of the sensors are the goal of this system.

Through intensive development work, the chemical compositions of our solutions have been adjusted optimally to the **ESCHWEILER** sensors and guarantee, besides precise measurements, the greatest possible protection of the sensitive sensor surfaces.

For example, special wetting solutions are used which have a decisive influence on the unconstrained contact between sensor and solution in the measuring capillary. At the same time suitable preservatives prevent the growth of micro-organisms in the consumable solutions and keep them from being introduced into the measuring capillaries of the **ESCHWEILER** analysers.

The characteristics and concentrations of both the wetting- and the preservative substances are selected according to the special requirements of our sensors.

Fault-free operation of our analysers with measuring accuracy and long sensor life are the main goals of our quality requirements. Only if **ESCHWEILER** original parts and solutions are used we can meet these requirements.

Please support us in doing this!

Contents

! Safety Issues

Please read the Instruction Manual in its entirety prior to operating the **Combiline**. In order to ensure a high level of performance, all warnings and references to technical safety in this Instruction Manual have to be followed.

! 1 Hazards and Precautions

The cautions and safety regulations in this Instruction Manual meet international classifications:

DANGER

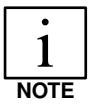
Warns of a risk of injury or of a risk to life (for example by electrical shock).

CAUTION

Warns of a risk of injury or of the analyser being severely damaged.

Biohazard

Warns of a risk of biological material like blood or other human or animal specimen. Risk of infection! Potential infectious area/material!



NOTE

Introduces rules to be observed.

The following safety issues have to be observed at all times:

Electrical safety

DANGER

- Check that **the operating voltage is set correctly** before you connect the device to the main power supply.
- To connect the analyser to the main power supply, use only sockets which are **grounded** to avoid the risk of an electrical shock.
- Use only **grounded** extension power cords. The used power cord has to correspond to the **country specific regulations**.
- **Never** intentionally **disconnect** the grounding contacts**.**
  There is the risk of electrical shock if the protective conductor is interrupted within or outside the analyser, and/or the grounded contacts have been disconnected from the line.
- **Never** remove protective guards or secured components since you could expose electrically live parts in this way.
- Electrical connection contacts (plugs, sockets, etc.) can be electrically live.

- Even after an analyser has been switched off, components (e.g. capacitors) can be under voltage as the result of an electrical charge.
- All current carrying parts are sources of danger for an electrical shock.
- Surfaces (floors, work tables) have not to be moist when you are working with any electrical device.
- Carry out **only** the maintenance work and/or the replacement of parts described in these Instruction Manual.
- Unauthorized work on the analyser can lead to the guarantee obligation becoming null and void with necessary expensive service work to correct it.
- All work, which requires the analyser to be opened, **have to be carried out by an authorised technician** who is familiar with the risks related thereto.
- Use **only replacement fuses** of the stated type and with the stated nominal current. Never use fuses, which have been “repaired”.
- There is a **Lithium battery** on MAIN BOARD **that have to be replaced by the authorised technical service every 5 years**! In case of a battery fault, all memorised parameter might be lost.

Mechanical Safety (Analyser is operating)

CAUTION

- Never open or unscrew analyser's casing parts while it is switched ON. There is a risk of injury due to moving parts as fans, pumps, stepper-motors or any other mechanical movements.

Biological Material - Risk of Infection

Biohazard

- Wear gloves in all cases if there is a risk of infection.
- Avoid any direct contact with samples that are potentially infectious or which may generate other risks to the human body (**Aids**, **Hepatitis** etc). In case of direct body contact go and wash the contaminated area immediately. Use a suitable skin disinfection solution. Ask your doctor for aid.
- If sample material (blood) or reagent is spilled onto the analyser, wipe it off immediately and refer to the chapter **! 2 Maintenance and Hygiene**.
- Do not open a waste bottle as long as the analyser is in process.

Reagents and Controls

- Observe the suggestions in the package inserts for an exact use of the reagents and quality controls. Note that reagents and quality control material can be biological material!
- Don't use Reagents, Controls and other Liquids after expiration date!
- Avoid any liquid penetration into the analyser.

Restrictions for Samples, Reagents and Controls

- For consumables no guarantee can be provided for any resistance against organic solvents. For this reason, do not use any organic solvents unless such solvents are expressly indicated.
- Do not use any other rinsing or cleaning solutions as recommended by the manufacturer or representative.
- Waste liquid has to be disposed in compliance with the legislation.

Accuracy and Precision of the Measured Results

- In order to ensure a flawless operation of the analyser measure control samples and watch the function of the analyser closely.
- Faulty measurement results may result in an incorrect diagnosis or range danger for patient.

Fire and Explosion Hazards

- Do not place any flammable or hazardous explosive material in the proximity of the device. Electrical sparks could cause fire or explosions.

Operator Qualification

- The analyser **should only be operated** by trained personnel. Improper operation of the analyser might cause inaccurate measuring results!

! 2 Maintenance and Hygiene

- No **organic acid** based cleaning substances should be applied. Instead use cleaner designed for cleaning and disinfecting laboratory analysers. **Only use** a dampened cloth to clean the analyser.
- **Never spray** or pour cleaning solution directly onto the analyser, that may negatively impact the analyser's functions significantly.
- Keep the analyser clean and **do not spill liquids** onto it.
- In case liquids were spilled onto the analyser, immediately absorb liquid with a suitable cloth.
- Contact your distributor if your control measurements do not produce the expected results.

Recommended Disinfectant Solutions.

A suitable disinfectant is available by BODE Chemie, Hamburg: **Bacillol®**, is recommended for areas at risk of infection, where **rapid contact times and drying times are necessary.**

BODE Chemie GmbH & Co
Melachtonstr. 27 - 22525 Hamburg, Germany

Phone: +49- (0)40-54 00 60 - Internet: www. bode-chemie.de

Another suitable disinfectant is available by S&M Schülke & Mayr: **TERRALIN® Liquid**

Schülke & Mayr GmbH
Robert-Koch-Str. 2 - 22851 Norderstedt, Germany

Phone: + 49- (0)40-521 00-0 - Internet: www.schuelke-mayr.com

See the website for your nearest representation. Ask for an EC Material Safety Data Sheet according to EC 91/155.

! 3 First-Aid Measures

If a person swallowed any chemical solution may be while servicing, wash out mouth with water.
If provided person is unconscious, **than call a physician**.
If inhaled, remove to fresh air. If breathing becomes difficult, **than call a physician**.
In case of contact, immediately wash skin with soap and copious amount of water.
In case of contact with eyes, flush with copious amounts of water for at least 15 minutes.
Assure adequate flushing by separating the eyelids with fingers, **than call a physician.**

! 4 Repairs


CAUTION

- Repairs to the analyser may only be carried out by trained personnel, and replacement parts have to comply with the analyser specifications.
- In case of analyser problems contact your representative.

Useful hint


NOTE

In this Manual a bullet "•" draws your attention to an instruction. Example:

• Press enter-key to confirm ...

1 Introduction

1.1 Intended Use

IVD

The **ESCHWEILER Combiline** is a microprocessor-controlled automatic analysis system for quantitative measurement and calculation of pH-, electrolyte-, haemoglobin- blood gas- and metabolite parameter of a single sample of human whole blood or serum.
The Combiline is intended for use by trained operators in hospital labs and/or specialist doctor's offices for in-vitro-diagnostics.

1.2 System Description

Functions

The samples are inserted directly into the Sample-Port from capillary tubes, syringes, vacutainers or other sample-intake systems.

The material to be measured, is automatically sucked into the analysis system from capillaries and is injected from syringes, into which can be seen from outside window.
The sample quantity needed, to fill the analyser system completely, is controlled by a Light Barrier. The sample volume is approx. 50-150µl depending on the model type.

The analysis system consists of individually replaceable Sensor modules. The thermostating at 37.0 °C ± 0,2 is done by a solid-state thermostat and is not software controlled (refer to chapter 3.5.2.6).
The calibration of the Sensors is fully automatic or can be carried out manually.

Sample- and calibration waste is collected in a disposable Waste Bottle with a filling level control. Empty Wash Solution Bottles are used as Waste Bottles.

Operation

The Combiline is operated with the help of a menu-controlled dialogue by Soft-keys and a 16-line LCD display. By this Keypad inputs such as changes in the standards (Hb, FIO_2 and RQ), the calibration parameter or the date and time can be made.

In the SERVICE menu / REAGENTTEST the individual functions are carried out as long as the corresponding key is pressed.

If a Calibration Solution Bag or Bottle is empty, this is shown in the display. After a new bag or bottle has been replaced and the QUIT-key has been pressed, the analysis system is ventilated automatically. The Combiline is then ready for use again.

If the Waste Bottle is full, this is also indicated. After the Waste Bottle has been replaced, the Combiline is ready to measure again.

Generals

At all times the Combiline remains switched ON and is continuously calibrated in a programmed cycle. In times of reduced sample activity, for example at night, the Combiline can be operated in an Economy mode with extended calibration cycle times.

All Sensors can be switched ON or OFF individually by the user as needed. The system remains ready for operation. It is also possible to select the computed values which are to be expressed individually.

Maintenance

Several easily operated test- and function programs are available for the user, which make it possible to localize functional disturbances quickly. The operability of the Combiline and the Sensors is monitored automatically and continuously. Irregularities, for example in the function of the Sensors or the supply with working materials, are indicated at once.

1.2.1 System Overview and Terms

The Combiline

Dialogue Area consists of:
LCD-Display and Keypad
Built-in Printer

Support Area consists of:
Wash- and Waste Solution Bottle
Combiline BGA: Waste Bottle, BGA1, BGA2, WASH1
Combiline ISE: Waste Bottle, CAL3, CAL4+M, WASH2
Combiline BGA+E: Waste Bottle, WASH2, BGA3, BGA4, CAL3, CAL4
Combiline meta: Waste Bottle, WASH2+M, BGA3, BGA4, CAL3, CAL4+M

Analysis Area consists of:
Sample Port
Sensor Array, thermostated at 37.0 °C

Figure 1 Combiline, front view

Dialogue Area

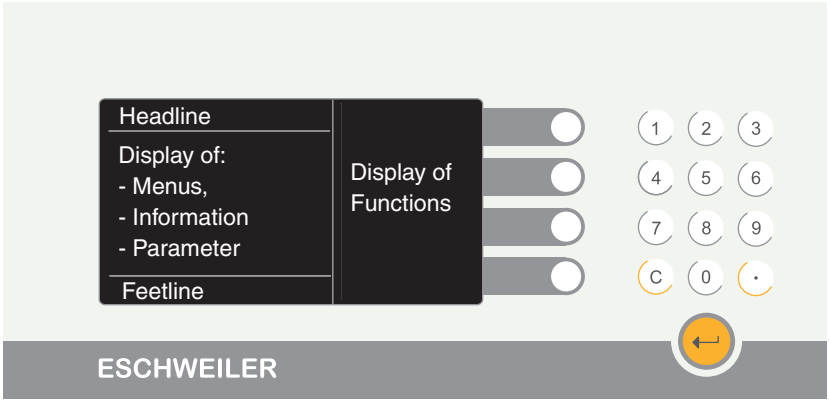


Figure 2 Dialogue Area

LCD Display

Software dialogues are shown by the 16 line (30 characters each) LCD Display which is back-lighted. The contrast is adjusted by the manufacturer and can be readjusted by the Technical Service only.

The software dialogue appears in four sections on the display.
The **headline** (upper section) indicates the analyser status and actions e.g.: STAND BY, WARM UP PHASE, CALIBRATION DATA etc.

In the middle section, between headline and feetline the software indicates Software menus, measured results, system parameter etc.

The **feetline** (lower section) indicates the system time on the left side (e.g.: 14:27) and the timer countdown for the next automatic system calibration (e.g.: CAL 25 min) on the right side.

The right section indicates **functions** to be carried out by pressing the corresponding right hand Soft-Key like e.g.: OPERATION, START CALIBRATION, QUIT etc.

Keypad

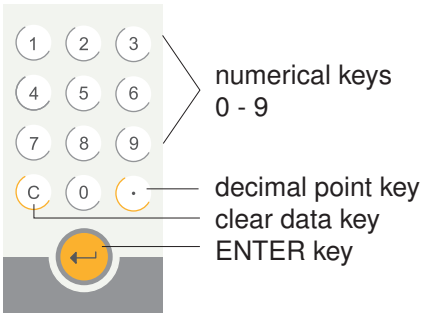


Figure 3 Keypad

With the numerical keys all number entries can be made in dialogues, except during measurement.

For example:

- sample identification number.
- FIO_2- and RQ-values.
- values for configuration of the analyser, such as calibration parameter or time and date.

Decimal point key

With this key **commas** and **decimal points** required for numerical entries can be entered.

Clear data key

With the correction key "**C**", numbers entered in an activated menu can be deleted. This makes a new entry possible without opening the dialogue again.

Built-in Printer

The built-in printer and its thermal paper (56 mm wide) are located on upper side of the Combiline.
A red stripe on the left side of a print-out indicates that the paper supply is only sufficient for a few more print-outs. For paper replacement refer to chapter 3.7.4, for technical details refer to chapter 7.5

Beeper

A sound is heard by a beeper:
- after switching the power ON
- after specimen is detected by a light barrier
- to remove a syringe or capillary from Sample Port

Analysis Area

The white cover can be taken down to access the analytic parts.

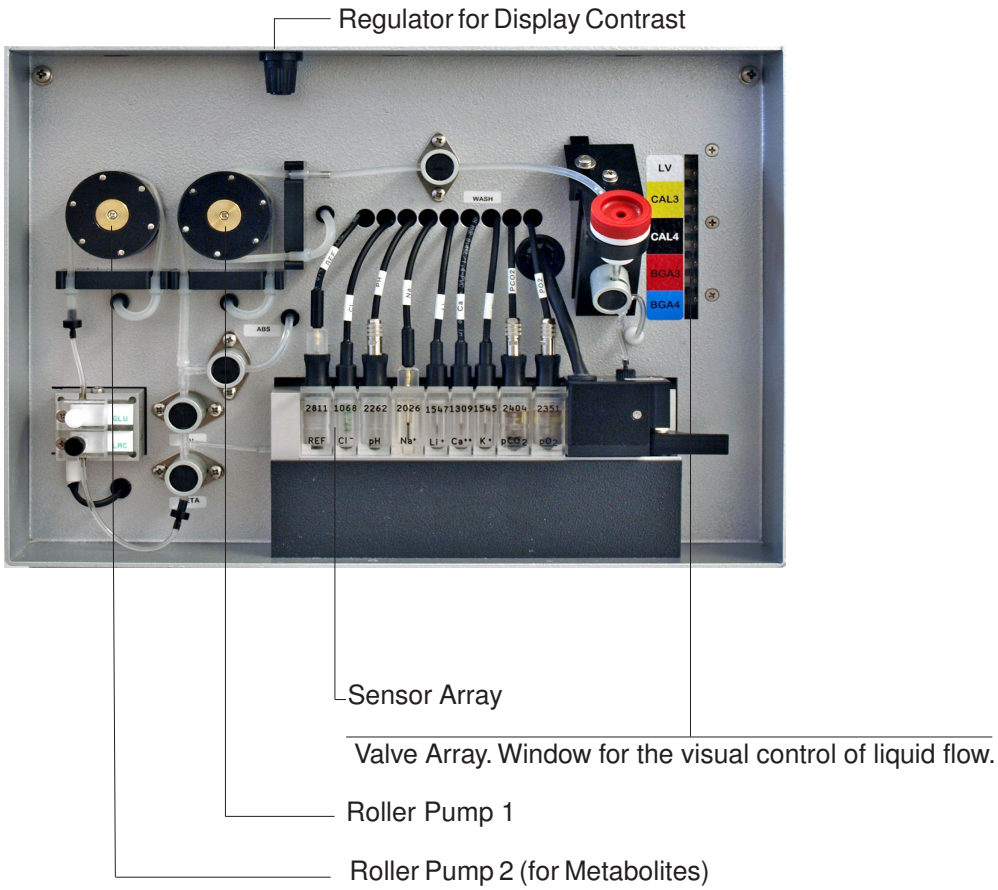


Figure 4 Analysis Area

Sample Port

The Sample Port is designed for the use of syringes, capillary tubes, vacutainers or other sample-intake systems.
It is equipped with a tube for washing or cleaning purposes.

Sample introduction by a capillary

To start a measurement of a capillary sample, press MEASURE key and follow the display dialogue.
Insert capillary into the Sample Port until a resistant is given. The capillary is automatically guided to the analysis system (metal canula). After pressing the ENTER key, the sample is aspirated automatically from the capillary.

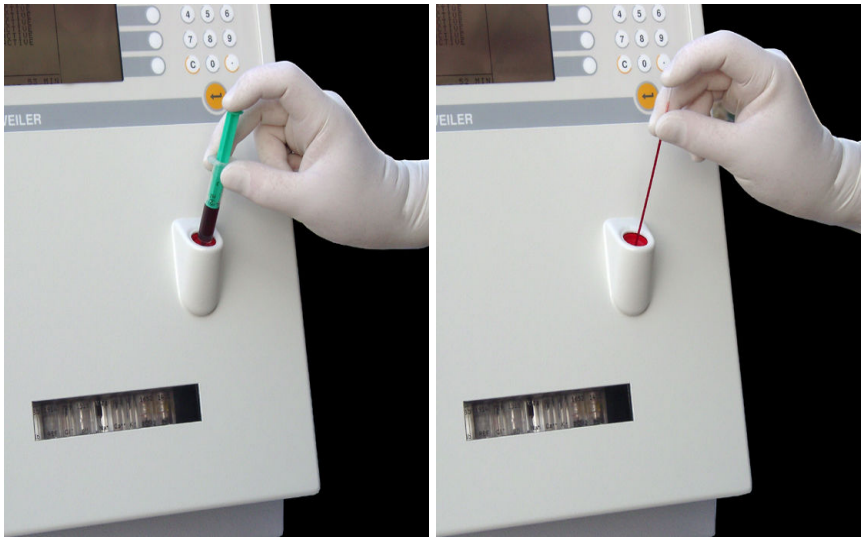


Figure 5 Sample Port and sample introduction

Sample introduction by a syringe

To start a measurement of a syringe sample, press MEASURE key and follow the display dialogue.
Insert syringe into the Sample Port and inject sample material slowly into the Port until you hear a beep-sound. Remove the syringe from the sample port after the second beep-sound.

NOTE

Before introducing a syringe into the Sample-Port, make sure that the syringe is filled completely and without air-bubbles!

Sensor Array

The Sensor Array is the central unit of the analysis system and is thermostated at 37.0 °C ± 0.2. The Combiline can be equipped with different Sensors depending on the customer's needs.
If the analyser is equipped with a Haemoglobin-Sensor, it is installed on the left side of the array.

Release the Sensor Catch lever only for Sensor maintenance, otherwise the analysis system is open! Make sure that the analyser system is closed!

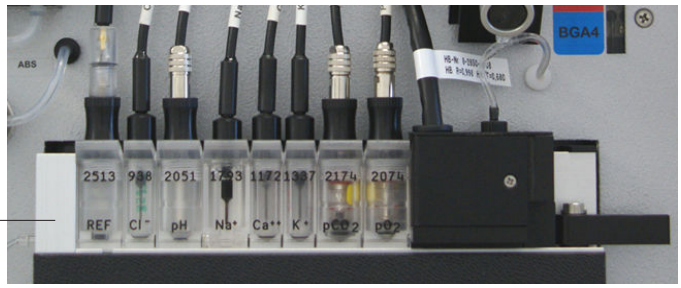


Figure 7 Sensor Array

A Sensor Catch is located beside the Ref.-Sensor whitch locks up the liquid system of the Sensor group. If any liquid is flowing through the analysis system, a back-light is on to display the liquid flow and possible sediments can be seen. For more information about the Sensors refer to chapter 6.2 Maintenance of Sensors.
The light barrier (LB2) at the end of the Sensor group controls the flow of the Calibration- and Washing solution and also the filling level of an introduced sample. (LB1 is out of function).

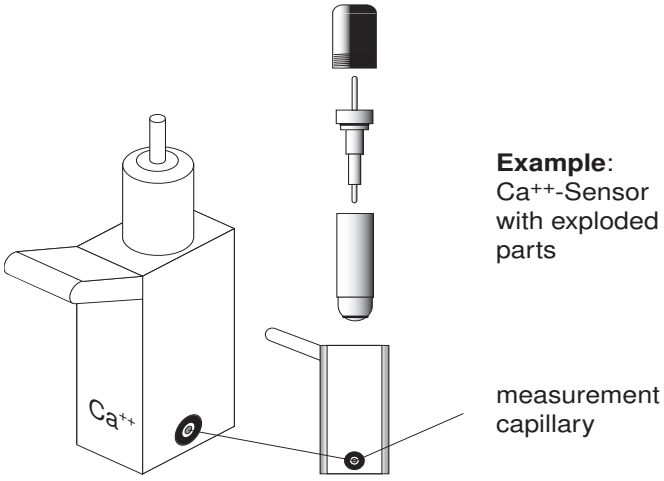


Figure 8 Calcium-Sensor (example)

Support Area

The Combiline carries out Sensor calibrations automatically in a preprogrammed cycle of 90 min, but in ECONOMY mode in a cycle of 240 minutes.
To determine the relationship between the Sensor signals and the partial pressure and ISE values of samples, the Combiline uses high and low level Calibration Solutions.

NOTE

For determination of Blood-Gas results, calibration solutions BGA1 and BGA2 are used in the COMBILINE BGA. For this BGA3 and BGA4 are used in the COMBILINE BGA+E and versions with metabolites. For determination of the electrolyte concentrations the calibration solutions CAL3 and CAL4 are used in COMBILINE BGA+E and COMBILINE ISE

BGA: **b**lood **g**as **a**nalysis; ISE: **I**ons **s**elective **e**lectrode;
meta: metabolites

Calibrator Solution Bags and Wash Solution are consumables, see chapter 7.1 List of Consumables.

Calibration Solution Bags

The bags are connected to the analysis system by the bag's **Septum** to the corresponding Adaptor. **Don't misplace Bags!**
The Adaptor with a Slide Bar is named after the corresponding Calibration Solution Bag and is software controlled by a light barrier.

NOTE

Use only ESCHWEILER Calibration Solutions for COMBILINE analysers, otherwise disturbances could appear or results could be wrong!

Refer to chapter 3.7.1 for the replacement of Calibration Solution Bags.
Don't replace a Calibration Solution Bag while the COMBILINE is powered OFF!
If a Calibration Solution Bag is empty this is shown on Display.

Figure 9 Support Area COMBILINE BGA

In COMBILINE BGA the **Calibration Solution Bag BGA1** serves for determining the low Sensor signal (lower calibration point) of the pCO_2 and pH. The **Calibration Solution Bag BGA2** serves for determining the high Sensor signal (upper calibration point) of the pCO_2 and pH.

In COMBILINE BGA+E and all metabolite versions the **Calibration Solution Bag BGA3** serves for determining the low Sensor signal (lower calibration point) of the pCO_2.
The **Calibration Solution Bag BGA4** serves for determining the high Sensor signal (upper calibration point) of the pCO_2

In COMBILINE ISE, BGA+E and all metabolite versions the **Calibration Solution Bottle CAL3** serves for determining the low Sensor signal (lower calibration point) of the ISE and pH sensors.
In COMBILINE ISE and BGA+E the **Calibration Solution Bottle CAL4** serves for determining the high Sensor signal (upper calibration point) of the ISE and pH sensors.
The calibration parameter are stored in the internal memory.

Figure 9 and 9a Support Area Combiline BGA+E / Combiline meta

	CAL3	CAL4+M	CAL4
K^+	1.80 mmol/l	5.50 mmol/l	5.50mmol/l
Na^+	110 mmol/l	155 mmol/l	150 mmol/l
Ca^+	0.50 mmol/l	1.50 mmol/l	1.50 mmol/l
Cl^-	90 mmol/l	130 mmol/l	130 mmol/l
Li^-	0.35 mmol/l	2.0 mmol/l	2.0 mmiol/l
pH	6.91	7.38	7.38
GLU		5.00 mmol/l	
LAC		5.00 mmol/l	

Table 1 Concentrations of CAL3 and CAL4 +M and CAL4

NOTE

The concentrations given in table 1 for CAL3, CAL4+M and CAL4 are continually stored in the internal memory of the Combiline.Therefore solutions with different concentrations cannot be used!

The Bag's label indicates the name of the Calibration Solution and the
- order number
- charge number
- expiration date
- CE-mark
- content of 130 ml
- storage condition at 18-25 °C
- standard values

Consumption of Calibration Solutions

The Combiline needs for every calibration process 0.8 ml Calibration Solution from each bag / bottle.

Wash Solution WASH1 / WASH2

One bottle of WASH1 contains 330 ml of WASH1 Solution. One bottle of WASH2 contains 250ml of WASH2 Solution in combiline BGA+E and 330ml of WASH2 in combiline ISE. It is absolutely necessary for cleaning the Sample Port, the analysis system and at last all tubes.

Wash Solution WASH2+M

One bottle of WASH 2+M contains 250ml of WASH2+M Solution. WASH+M is used in combiline meta only.It is absolutely necessary for cleaning the Sample Port, the analysis system and at last all tubes.


CAUTION

Use only original ESCHWEILER Wash Solutions for Combiline analysers, otherwise disturbances could appear or results could be wrong!

The Wash Solution Bottle has to be replaced when the message WASH SOLUTION/PLEASE CHECK is indicated on Display. The empty Wash Solutions Bottle must be used for the Waste Bottle replacement. For replacement of Wash Bottle refer to chapter 3.7.2. The WASH2+M SOLUTION Bottle is controlled by a level Sensor!
The bottle's label indicates the name of the solution and the

- order number
- charge number
- expiration date
- amount
- storage condition at 18-25 °C
- CE-mark

Consumption of Wash Solution WASH1 and WASH2

The Combiline needs for every washing cycle 2.0ml WASH1 or WASH2 Solution.

Consumption of Wash Solution WASH2+M

The Combiline needs for every washing cycle 3.0ml WASH2+M Solution.
A washing cycle will be performed automatically after every measurement.
If there is no measurement requested after 10 min of the last measurement or calibration process, the analysis system will be filled with 0.7ml Wash Solution until the next measurement is requested or a calibration process is started automatically by the software.

Waste Bottle

The Waste Bottle adapter cap is equipped with a level Sensor. A full Waste Bottle is indicated on Display: WASTE BOTTLE / PLEASE CHECK. It is recommended to replace the full Waste Bottle with an empty Wash Solution Bottle. Refer to chapter 3.7.3 for the replacement of the Waste Bottle.

The cap must be cleaned and decontaminated regularly in accordance to the maintenance schedule!


CAUTION

Note that the content of the Waste Bottle is potential infectious biological material. Wear suitable GLOVES if you intended to replace the Waste Bottle to protect yourself!

Disposal of Waste Solution


Biohazard

Biological material has to be disposed off in accordance with the national guidelines for the disposal of biological material!

Solution summary

designation	amount	order no.
COMBIline BGA		
WASH 1	330ml	40 6 10 00
BGA 1	130ml	40 6 10 20
BGA 2	130ml	40 6 10 30
COMBIline ISE		
WASH 2	330ml	40 6 10 15 (3-4.110)
CAL 3	330ml	40 6 10 60 (3-4.100)
CAL 4	330ml	40 6 10 65 (3-4.500)
COMBIline BGA+E		
WASH 2	250ml	40 6 10 10
BGA 3	130ml	40 6 10 40
BGA 4	130ml	40 6 10 50
CAL 3	150ml	40 6 10 45
CAL 4	150ml	40 6 10 55
combiline meta		
WASH 2+M	250ml	40 6 10 11
BGA 3	130ml	40 6 10 40
BGA 4	130ml	40 6 10 50
CAL 3	150ml	40 6 10 45
CAL 4+M	150ml	40 6 10 56

Rear side

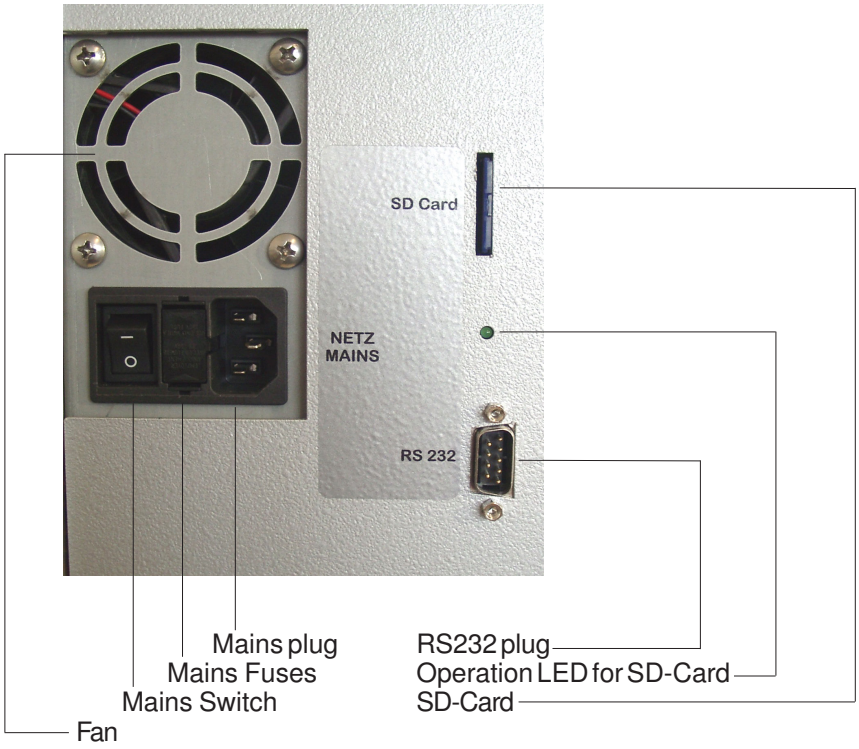


Figure 10 Rear View

Power Connection

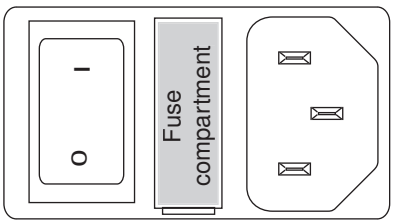


Figure 11 Power connector/Fuse compartment

The Power connector is located at the rear side of the Combiline and contains:
- the Power Switch ON = I/OFF = 0
- fuse compartment (for replacement refer to chapter 6.4)
- a cold device plug

Power Requirement

Note that the mains voltage must meet following requirements
The **necessary** operating voltage is indicated on the Type Plate.

Voltage	Frequency	Main fuses
115 - 230V~	50/60 Hz	2 x 250 V T2,5A time lag

Please observe Type Plate on the rear side!

CAUTION

The Combiline has to meet the local requirements! If not, don't use it and call for the Technical Service!

CAUTION

The Main Cable used has to meet the local regulations (e.g. VDE, CSA-C22.2, no 21 and no 49). The cable has to be designed with NYLHY. The recommended length is 0.5 m, and the minimum cross-section is 3 x 0,75 mm².

Model Type Identification

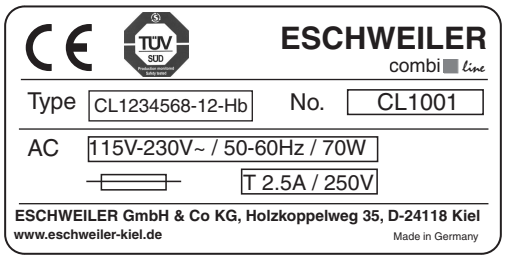


Figure 12 Type Plate

The Combiline Type Plate indicates:
- CE Certification
- SNo.: Combiline Serial Number
- VA: Max. power consumption
- Manufacturer Address
- Type: Combiline xx
- Volt: Operating voltage
- Hz: Power frequency
- Internet Address

Model variations

Combiline BGA	= BGA (Blood-gas)
Combiline ISE	= ISE (Electrolytes)
Combiline BGA+E	= BGA + ISE
Combiline BGA HB	= equipped additionally with Hb-Sensor
Combiline BGA+E HB	= equipped additionally with Hb-Sensor
Combiline meta	= equipped additionally with metabolites
Combiline meta HB	= equipped with metabolites and Hb-Sensor

Fan

The system is protected against overheating by two cooling fans. They are running continuously. At the rear side of the Combiline one fan is equipped with a dust filter which has to be replaced regularly, see chapter 6.5.

RS232 Interface

The Serial interface RS232 can be used for the data transfer to the host computer. Refer to chapter 7.7 for the interface description.

Labels

A yellow label is located at the Mains Connector to indicate high voltage.

A white/blue label indicates **TÜV SÜD** ; i.e. the analyser is tested about safety.

1.2.2 Functional Description

The Liquid System is a closed system, in which calibrations will be performed automatically in programmed cycles. Calibration Solutions, Air and Wash Solution are transported through the Sensor unit by a Pump and several Control-Valves.
The transportation of a sample and other solutions is guaranteed by an electronically controlled Roller-Pump and with help of light-barriers.

By pressing the MEASURE soft-key the system prepares for the introduction of a sample by the use of a Syringe or Capillary. Further instructions about the procedure will be shown on display.

A **Capillary** is coupled to the Liquid System (metal canula) automatically by the Sample Port Guide. The suck in of the sample will take place automatically after pressing the ENTER key.
A **Syringe** is coupled in the same way, but the sample must be injected into the Port manually.
The measuring process is normally completed after 45-60 seconds, the results are shown automatically and are printed out.

The sample material, or in the case of a calibration the Calibration Solution, will be sucked out by a Vacuum-Pump and is guided into the Waste Bottle with the help of Control-Valves.

After a measurement, an automatic washing cycle takes place in order to clean Tubes, Sample Port and Sensor capillaries.

The Vacuum Pump produces only a low pressure, (no liquid is transported through) for the fast disposal of sample material, Wash- or Calibration Solution.

Moisture, that possibly reaches the Vacuum Pump, is intercepted by the Moisture-Absorber, this must be controlled regularly and emptied manually if necessary by the service stuff.
While transporting liquids, the Sensor-Array is background-illuminated in order to be able to recognize disturbances in the flow as well as sediments. Protein-sediments can cause potential-changes at the Sensors, regular maintenance-measures are therefore necessary.

1.2.3 Specimen Collection

Procuring a sample

Proper extraction and handling of blood samples before the analysis for blood gas analytical determinations are extremely important, in order to assure that the measured values received correspond to the actual (real) blood conditions.

NOTE

It is recommended to contact professional workgroups in other hospitals to exchange knowledge and experience with them regularly to be up to date.

Use of heparin

Use only heparinised sample collecting devices (syringes or capillaries)!
If the Combiline is equipped with
- Na^+-Sensor, don't use Na^+-heparin!
- Li^+-Sensor, don't use Li^+-heparin!

In these cases use **ammonia-heparin** with a concentration of 80 ie/ml vol. Otherwise corresponding measuring values could be wrong!

Arterial blood

Samples for pH- and blood gas analysis are preferably taken from an artery. Usually the extraction is accomplished through puncture of the arteria femoralis, -brachialis or -radialis. Through catheterizing and surgical operations, however, access to other arteries is also possible.
Use of venous blood samples has found its way into clinical laboratories to some extent, but it must be kept in mind that although the material procurement is simpler in comparison to arterial puncture, venous blood can only be used when parameter of the metabolic components alone are to be determined.

Syringes

The samples are taken in airtight glass- or plastic syringes. Glass syringes are used more frequently because the easy-action plunger reacts passively to the arterial pulsation of the flowing blood.
The syringe plunger must, however, be coated with paraffin oil on the sides to seal it, and then the clearance volume must be filled with heparin free of air bubbles. Other anticoagulants such as Citrat, Oxalate, EDTA cannot be used because they shift the electrolyte values and pH-value and thus considerably distort the acid-base parameter. When plastic syringes are used, the clearance volume must also be filled with heparin. The gas permeability of most synthetic syringes, however, represents a source of error for O_2 and CO_2, so that the analysis should take place immediately after extraction. The time of the analysis can be extended up to 2 hours for cooled samples.

Venous blood

When puncturing a vein, the following points must be observed: If a tourniquet is used, extraction must follow quickly, because a haemostasis causes a rise in the capillary pCO_2 and a reduction of the pH. During extraction the tourniquet must not be loosened, the fist should not be closed and no pumping should take place. Since the venous blood permits only a limited statement about the acid-base household, this method has been largely replaced through the capillary technique.

Arterialized capillary blood

Procuring of arterialized capillary blood from the periphery is relatively simple. Capillary blood, which is extracted after hyperaemia through puncture of the skin, corresponds in its composition with arterial blood, since it comes mainly from arteriols. The skin is preferably punctured in the ear lobe, in infants in the heel. The blood must flow freely and in sufficient quantity. The point of extraction should not be pinched, because this leads to the addition of blood from the venol and of tissue fluid, distorting the results.

Local hyperaemia can be achieved mechanically, thermically or chemically. Chemical hyperaemia using Finalgon salve or Rubriment oil has been proved very effective. After application, it should be allowed to react for 5-10 minutes, then rubbed off with dry tissue paper, then wiped off with 70-80% alcohol. After the puncture using a one-way stiletto, discard the first drop and catch the blood which then flows out spontaneously in heparinized capillaries, free of air bubbles.

Capillaries

Extraction is done according to the method recommended by Siggard-Andersen. The horizontally-held capillary is introduced into the middle of the drop of blood to avoid contamination with air. The capillaries are closed after being filled and the blood thoroughly mixed with heparin. The two ends of the capillaries are closed with plastic caps, and the capillaries are then rolled between the palms of the hands. This assures an excellent mixture of blood and heparin.(See chapter 3.2)

Storage of the samples

In storing the samples it must be kept in mind that metabolism continues to take place after extraction. For the metabolism of the cells, especially the leukocytes, sour metabolites (e.g. milk acids) are formed, which alter the acid-base parameter. The degree of this acid formation depends on the number of leukocytes and especially on the temperature.

With a normal number of 5000-10.000 leukocytes/mm^3 blood, analysis should take place within 15-20 minutes. Through cooling at 0-4 °C the period can be extended up to 2 hours. Furthermore the pCO_2 will fall because of the temperature reduction, so that the gas exchange is facilitated by the lower partial pressure slope to the atmosphere.
If, in the case of longer storage below the measuring temperature, the plasma is separated and the measurement is then carried out at a higher temperature, the results are a higher pH-value and lower gas values than in whole blood. The logical consequence is that the erythrocytes must be resuspended before warming up to measuring temperature (that is before the sample is put into the analyser).

1.2.4 Storage of Standard Data

How to understand Standard Data:

Standard Data are parameter which are entered in the Menu STANDARD DATA e.g. Calibration data, Date and Time etc.

The Standard Data of the Combiline are stored in an internal memory buffered by a Lithium-Battery. This means that the **Standard Data entered by the user** are saved in the memory during brief power interruptions or if it is switched off manually.

Combiline was switched off for less than 8 minutes
When the Combiline is switched on again, a calibration is carried out automatically using the Standard Data, which have been entered previously.

Combiline was switched off for less than 24 hours
In this case all manually entered data are still saved in the memory. After switching on, the analyser starts the Warm-Up Phase. After that a calibration follows automatically using the Standard Data, which have been entered previously.

Combiline switched off for more than 24 hours
After power on, the analyser requires the parameter for BGA 1 / 3 and BGA 2 / 4 by showing the Calibration Data dialogue as long as the parameter are entered.
The parameter for Hb (haemoglobin) are still saved in the memory.
All previously entered **Standard Data are returned** to the values programmed by the factory **except** Date and Time. The Combiline is calibrated automatically after a one-hour Warm-Up Phase. Standard Data can be changed manually during the Warm-Up Phase.

Factory settings (standard-configuration)

Unit: Partial pressure = mmHg, Metabolites = mmol/l
HB-Standard: 15g/dl
FIO2: 20.9%
RQ: 0.85
Printouts: 1
Correlation: 1,000 (pH = 0,000)
Electrodes: ACTIVE (all)
Hb-activation: Hb-sensor not active
Calibration Data pCO2/pH*: must be set by the operator!
* only for Model types with pCO_2- and pH-Sensor!

1.2.5 Software Overview

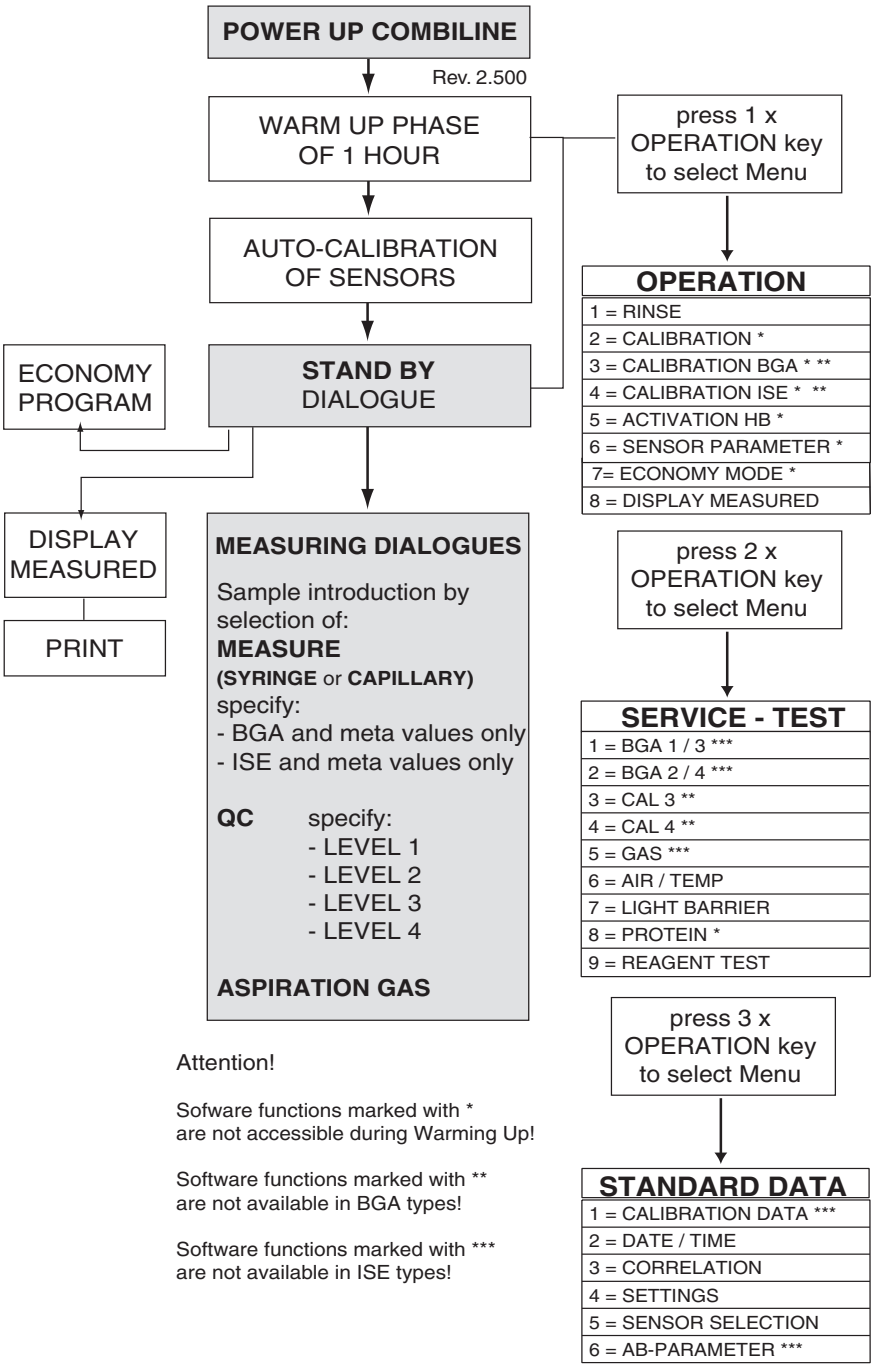


Figure 13 Software Overview

1.3 Power Up Procedure

This chapter explains what the Combiline is doing after switching on, what dialogues appear and what functions will be performed until the STAND BY dialogue appears.

CAUTION

Power up the Combiline only after the installation procedure as described in chapter 2.3.

Switching ON

- Set the Power Switch on the rear in position **I**.

NOTE

Only if the Combiline was switched off for more than 24 hours, a dialogue appears first to enter the BGA 1 / 3 + BGA 2/4 values. See chapter 1.2.4.

The following dialogue appears for about 3 seconds.

NOT READY	RESTART
PLEASE WAIT	RESET

As long as this dialogue appears you can press the corresponding soft-key:

- **RESTART:** The analyser will warm-up. All entered parameters and all settings made are present in the memory.
- **RESET:** The analyser will warm-up. All parameters and all settings are reset to the manufacturer settings. The analyser demands the input of the parameter for the Calibration Solutions BGA 1 / 3 and BGA 2 / 4.

The WARM UP PHASE dialogue appears as shown below.

WARM UP PHASE		PROGRAM
PO2	= ACTIVE	
PCO2	= ACTIVE	
PH	= ACTIVE	
K	= ACTIVE	
NA	= ACTIVE	
CA	= ACTIVE	
CL	= ACTIVE	
LI	= ACTIVE	
GLU	= ACTIVE	
LAC	= ACTIVE	
HB	= OFF	START CALIBRATION
10:45	AUTO 54 MIN	

The dialogue indicates which Sensors are installed and if they are set to **ACTIVE** or not. Refer to chapter 3.5.3.6 Sensor Selection for an activation/inactivation of Sensors.

The feet-line indicates the **real time** and an **automatic Calibration** will be done in e.g. AUTO 54 MIN after warming up (count-down-timer).
By pressing the corresponding **OPERATION**-key again and again you can select one of the following submenus:

- **OPERATION**
- **SERVICE- TEST**
- **STANDARD-DATA**

to carry out different functions, see software overview figure 13. Functions which are marked with a star "*" cannot be carried out during warming-up.

By pressing the corresponding **START CALIBRATION** soft-key you can **shorten** the WARM UP PHASE. Use this function only after powering up again when the analyser is already warmed up! A calibration cycle will be performed at once. After that the STAND BY dialogue appears.

The Combiline will not allow a measurement during the WARM UP PHASE!

Calibration cycle

While calibration process high- and low level Calibration Solutions cause a different voltage on the Sensor-Membrane. The high- and low level voltages are stored in the internal memory constitute a two-point calibration curve to compute the results. The reason for longer calibration cycles are justified in the change of the membrane voltage caused by deposits on the Sensor-Membrane. The programmed calibration cycles are a compromise between cost and precision of results.

In **STAND BY** mode there is a preprogrammed automatic calibration cycle of 90 minutes, see feet-line CAL xx MIN. An automatic calibration cycle can be interrupted by introducing a sample.

In **ECONOMY** mode there is a preprogrammed cycle of 240 minutes. A calibration cycle cannot be interrupted!

The **duration** of a calibration process depends mainly on the condition of the Sensors and their membranes. The average length of time needed for a calibration is approximately 4-5 minutes.

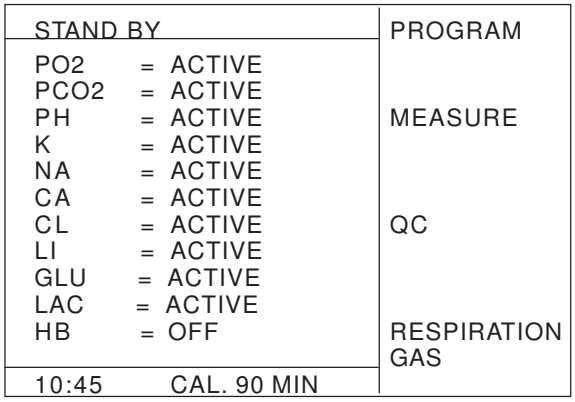
After 60 minutes when the WARM UP PHASE is over, a calibration cycle will be performed automatically. The following dialogue appears:

CALIBRATION
SOLUTION BGA3
SOLUTION BGA4
SOLUTION CAL3
SOLUTION CAL 4
SOLUTION CAL4+M
GAS
15:24

During this process every Calibration Solution and GAS/AIR will be aspirated for a Sensor calibration. A backlight is on for a while to allow a visual control of remaining liquid or sediments inside the transportation way of the Sensor's capillary.

Keep the white front-cover closed otherwise the temperature will be influenced and the calibration values of Sensors could be different! **Results can be wrong!**

When the calibration cycle is finished, the **STAND BY** dialogue appears:



This STAND BY dialogue should be seen as a MAIN MENU. The current system time appears and the countdown time for the next auto-calibration cycle.

All **further operations** you can carry out from here like:
- start different measurements by opening the Sample Port, see chapter 3 for detailed information.

- open submenus by pressing the corresponding PROGRAM-key to carry out different functions, see chapter 3.5 for detailed information.

- set the Combiline in ECONOMY mode, see chapter 3.6 for detailed information.

- display and print results, see chapter 3.1.1 for detailed information.

The STAND BY **dialogue will be changed** automatically:
- if an **error is evident**, refer to chapter 4 for detailed information.
- for a **calibration cycle**, refer to chapter 3.5 for detailed information.
- if a **Calibration Solution Bag** is empty, refer to chapter 3.7.1 for detailed information.

- if the **Wash Solution Bottle** is empty, refer to chapter 3.7.2 for detailed information.

- if the **Waste Solution Bottle** is full, refer to chapter 3.7.3 for detailed information.

2 Installation Procedure

CAUTION

Prior to the installation of the Combiline, read the instructions in chapter **! Safety Issues** first for your own safety!

CAUTION

The safety and functionality of the Combiline is guaranteed only if the Combiline is installed according to the operating instructions!

NOTE

The Combiline is intended for continuous operation and should be kept in operation all the time to insure high measuring accuracy!

2.1 Unpacking

Claims/Unpacking

If physical damage is evident or the Combiline does not meet specifications when received, notify the carrier and your nearest representative. Your representative will arrange for repair or replacement of the Combiline.
If the Combiline is to be shipped to a representative or service office, attach a paper showing the:
- owner's address,
- Combiline model type,
- Combiline serial number and
- repair required.

The original shipping material should be used. Your representative will provide information and recommendations on materials to be used, if the original packing material is not available or not reusable.

Mechanical Inspection

If external damage to the shipping box is evident, ask the carrier's agent to be present when the Combiline is unpacked.

• Check the Combiline and the accessories for external damage, such as dents or scratches on the analyser housing.

If damage is found, contact your representative immediately.
If the shipping box is not damaged, check the cushioning material for signs of severe stress as an indication of rough handling in transport. Retain the packing material for possible future use.

Provided Materials

See chapter 7.6 for a detailed list.

2.2 Operating Conditions

Ambient temperature: +12 °C to +32 °C (room temperature)
Relative humidity: 30-90%, no condensation

- Install the Combiline only in a suitable laboratory establishment.
- Keep the Combiline away from very strong electromagnetic influences!
- Beware the Combiline of mechanical vibrations.
- Place the Combiline in a sufficient distance from the wall so that connected cables cannot be pinched and the fan can work properly.
- Avoid big temperature fluctuations to protect condensation of water.
- Avoid direct sunlight.
- Avoid direct stream of an air conditioner.
- Install the Combiline so that the access to the mains-switch and the mains-connection is always possible.

NOTE

2.3 Installation Process

- Proceed the installation process in the following order **A**-**I**:

A Placement of Combiline

- Place the Combiline on a suitable laboratory table.

B Positioning and Control of Tubes

- Open the Orange Cover. (See figure 4)
  The two Roller Pump tubes are in a parking position to avoid mechanical stress.
- Proceed as described in chapter 6.8 and figure 32 for a proper installation of the Roller Pump tubes.

- Check if all visual tubes are free and do not pinch or snap.

The Sensors are already installed by the manufacturer and they are ready for operation (See figure 4 and 7).

C Installation and control of the Waste Solution Bottle

There is an unlabelled, empty Bottle supplied for the collection of waste liquids pre-installed by the manufacturer (see figure 14). **Check** if the cap is placed properly!

D Installation of the Wash Solution Bottle

- Replace the empty Wash Solution bottle with a new one supplied with the Combiline.

- Unscrew the cap (the bottles for Combiline BGS+E are supplied without screw cap). The cap will be used later to close the full Waste Bottle after its replacement. The Wash Solution bottle is closed by an aluminium film/coat.

- Cut the aluminium film crosswise with a scalpel and push the cut film into the bottle.

- Lift the Wash Bottle Adapter equipped with a long plastic tube.

- Insert the tube into the Wash Solution Bottle and put the Adapter flushing over the Bottle (see figure 14).

E Power Connection

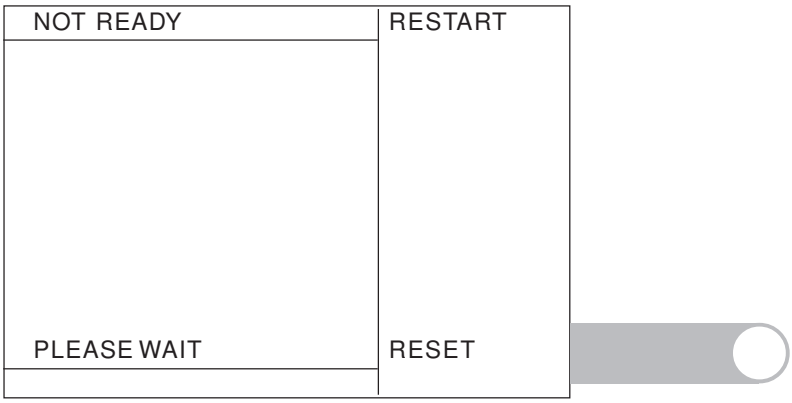
- Verify whether the Combiline meets the local power requirements as described in chapter 1.2.1 under Power requirement.

- Connect the Power Cord supplied between the Combiline and mains connection.

F Power ON - First setting into operation!

- Set the Power Switch at the rear in position **I**.

The following dialogue NOT READY appears for about 3 seconds.

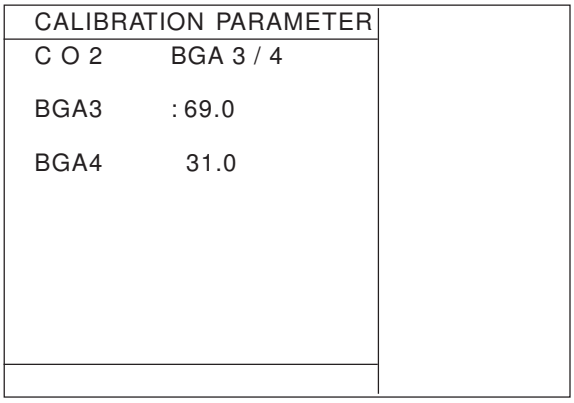


- **Press** the corresponding **RESET-key** within 3 seconds.
In case of passing this dialogue, switch the analyser OFF and ON again.

The **RESET**-function calls up the following dialogue for the input of the Calibration Bag's (BGA 1/3 and C2) calibration parameters.

G Input of Calibration Parameters

- Take the Calibration Bags supplied out of their packages.



example for Combiline BGA+E

Parameter for BGA 3 (BGA1) a colon appears behind BGA3:
(Not for Type Combiline ISE)

- Enter the pCO_2-parameter printed on the Calibration Bag **BGA3** (or **BGA1**) (red stripe) by numerical keys e.g. 69.0 [mmHg].

- Press **ENTER**-key to confirm.

Parameter for BGA4 (BGA2) a colon appears behind BGA4:
(Not for Type Combiline ISE!)

- Enter the pCO_2-parameter printed on the Calibration Bag **BGA4** (or **BGA2**) (blue stripe) by numerical keys e.g. 31.0 [mmHg].

- Press **ENTER**-key to confirm. The entered calibration parameters are stored in the internal memory now and the following dialogue appears:

WARM UP PHASE		PROGRAM
PO2	= ACTIVE	
PCO2	= ACTIVE	
PH	= ACTIVE	
K	= ACTIVE	
NA	= ACTIVE	
CA	= ACTIVE	
CL	= ACTIVE	
LI	= ACTIVE	
GLU	= ACTIVE	
LAC	= ACTIVE	
HB	= OFF	START CALIBRATION
10:45	AUTO 54 MIN	

HB is OFF !
It must be activated manually !

H Installation of Calibration Solution Bags

Type Combiline BGA+E: installation of Calibr.:-Solution BGA3 +BGA4 + CAL3 + CAL4!

Type Combiline meta: installation of Calibr.:-Solution BGA3 +BGA4 + CAL3 + CAL4+M!

Type COMBILINE BGA: installation of Calibr.-Solution BGA1 +BGA2 only!

Type Combiline ISE: installation of Calibr.-Solution CAL3 + CAL4 only!

NOTE

- Press the **Slide Bar BGA 1/3** on the Bag Adapter (**A**) to open the access to the corresponding metal canula (s. figure 15).
- Press the **Septum** (**B**) of the Bag BGA 1/3 against a small resistant over the metal canula.
- Release the **Slide Bar BGA 1/3** (**C**). The Septum is now fixed by the Slide Bar. A light barrier announces the placement to the software so that the Calibration Solution will be sucked in automatically.
- Proceed as described above for the installation of the remaining Calibration Bag **BGA 2/4**.

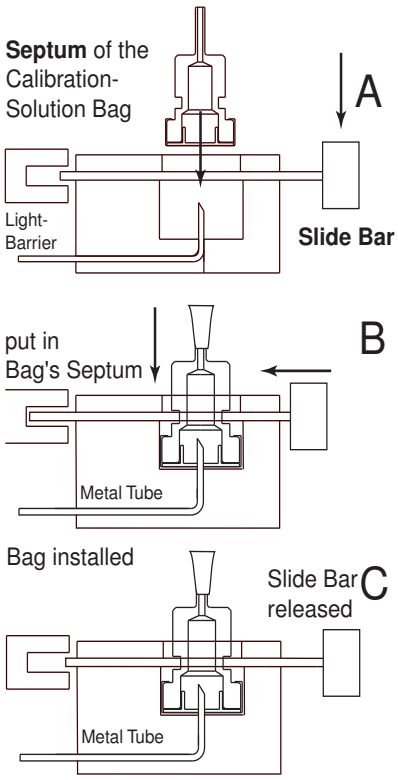


Figure 15 Installation of Calibration Solution Bags

NOTE

Just behind the installation of the Calibration Solution Bags BGA 1/3 and BGA 2/4 the dialogue for the input or control of the Calibration Parameters appears again. Check again if the parameters shown on dialogue meet the parameters printed on Bag's labels. False parameters can cause false results! If necessary, see step G for the input of Calibration Parameters.

If a problem should arise during transport of the Calibration Solution this will be indicated on display e.g.:

SOLUTION BGA 3	QUIT
PLEASE CHECK	

To solve the problem, refer to chapter 3.7.1 for more information.

I Activation of the Hb-Sensor (If installed!)

If the analyser is equipped with an Hb-Sensor, proceed as described in chapter 3.5.1.5 **Calibration of Hb-Sensor**.

Ventilation of the Tube System

The air is automatically removed from the transport tubes of the WASH and Calibration Solutions when the analyser is set in operation and if the Bottles or Bags have been installed properly.

If no Calibration Bags or empty Bags are present, this is indicated in the dialogue. The Combiline cannot prepare for measurement then.

As long as the **WARM UP PHASE** appears, the Combiline is **NOT READY** for Measurement! An opening of the Sample Port will be ignored by the Software.

- Close the Cover of the Support Area.

End of Installation

2.4 Transport of the Combiline

Before transport of the Combiline, all liquid bottles must be removed from the analyser and their tubes must be evacuated by the use of the program **REAGENT TEST** in Service-Test menu (see chapter 3.5.2.9).

The waste bottle must also be emptied, see chapter 3.7.3!
To transport the Combiline, proceed as follows:

- Wear protective gloves for your safety.
- Move the Combiline to the edge of the table so that you can safely grip under the bottom part at the longer sides of the Combiline.

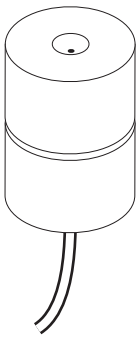
- To transport, carefully lift the Combiline with one person at each end. Be careful, there are screws beneath the analyser!

2.5 Storage of the Combiline

If the Combiline has to be put out of service, the Calibration Solution containers, Wash Solution Bottle and the Waste Bottle must be removed. In addition, the tube system must be emptied by the use of the program **REAGENT TEST** (see chapter 3.5.2.9) and the Roller Pump Tubes have to be removed from the Roller Body to avoid unnecessary mechanical stress.

Proceed as follows (analyser is powered on):

- Press the corresponding OPERATION-key two times to display the SERVICE - TEST menu.



- Press 9-key to display the REAGENT TEST dialogue.

For further operation take the **CSP-Adapter** (**C**alibration **S**olution **P**ort), a part of the Combiline accessories and a bottle filled with distilled water.

- Remove the Calibration Solution Bag BGA 1/3 and connect the CSP-Adapter instead. Put the tube into the distilled water bottle.

- Press the 3-key (for BGA 3) to suck distilled water for about 5 sec.
- Remove the tube out of the distilled water.

- Press the 3-key again for about 5 sec to suck the water out of the system.
- Proceed as described for the other Calibration Solution Bag BGA 2/4.
- Take the feeding tube of Calibration solution CAL3 and put it into the container with destilled water. Press the 5-key to suck destilled water for about 5 sec.
- Remove the tube out of the distilled water.
- Press the 5-key again for about 5 sec to suck the water out of the system.
- Proceed as described for the other Calibration Solution CAL4+M.
- Clean the cap of the Waste Bottle with a lint-free cloth and a suitable **disinfection solution** as recommended in chapter **! 2 Maintenance and Hygiene.**
- Clean/disinfect also the Sample Port Flap especially on its contaminated places. **Danger of infection!**
- Replace the Wash Solution bottle by an empty one.
- Dispose the Waste Solution in compliance with the legislations.
- Remove the tubes from the Roller Pump to avoid unnecessary mechanical stress.
- Protect the Combiline with a dust cover during storage or, if available, use the shipment box.

3 Measurement and Special Functions

CAUTION

At this point the operator should be familiar with the key-functions introduced in chapter 1 and the Combiline is installed properly as described in chapter 2.

CAUTION

It is absolutely necessary that only skilled persons should carry out measurements.

Sample introduction

Samples could be introduced into the Combiline in several ways:

- by syringe, see chapter 3.1.
- by capillary, see chapter 3.2.
- by Eschweiler aspiration pipe, see chapter 3.3
- by other containers for blood-gas diagnostic

Sample volumes required (approximately):

for syringe:	approx.: 500µl in the syringe	
for capillary:	combi*line* BGA:	70-85µl
	combi*line* ISE:	50-80µl
	combi*line* BGA+E:	80-140µl
	combi*line*^{meta} BGA:	120µl
	combi*line*^{meta} BGA+E:	100-150µl

Sample volumes required for analysers with Hb-sensor (approx:)

for syringe:	approx.: 500µl in the syringe		
for capillary:	combi*line* BGA+HB / BGA+E+HB	:	**120 - 200µl**
for capillary:	combi*line*^{meta} BGA+HB / BGA+E+HB	:	**200µl**

The required sample volumes are depending on the number of installed sensors.

NOTE

Use heparinized blood only! Eschweiler capillaries contain Ammonium-Heparin 80 ie/ml vol.

Keep a sample device with sufficient volume of sample material, free of air bubbles, ready!

See chap. 1.2.3 Specimen Collection for detailed information!

Measurements can only be carried out if the STAND BY dialogue is evident.

STAND BY			PROGRAMM
PO2	=	ACTIVE	
PCO2	=	ACTIVE	
PH	=	ACTIVE	MEASURE
K	=	ACTIVE	
NA	=	ACTIVE	
CA	=	ACTIVE	
CL	=	ACTIVE	QC
LI	=	ACTIVE	
GLU	=	ACTIVE	
LAC	=	ACTIVE	
HB	=	ACTIVE	RESPIRATION GAS
10:45		CAL. 90 MIN	

To carry out PROGRAM Submenu functions, refer to chapter 3.5.
To set the Combiline in ECONOMY mode, refer to chapter 3.6.
If an error occurs, refer to chapter 4 Error Messages.

If a Calibration Solution needs to be replaced or the Waste Bottle is full, refer to chapter 3.7 Replacements.

3.1 Using Syringe or Capillary

To run a measurement, proceed as follows:
- Press the MEASURE key. The following dialogue appears:

PREPARATION
PLEASE WAIT FOR SAMPLE INPUT REQUEST
12:15 CAL. 45 MIN

- Wait for approx. five seconds. The following dialogue appears automatically:

PREPARATION
S Y R I N G E INJECT SAMPLE SLOWLY AND WAIT TO REMOVE SAMPLE DEVICE C A P I L L A R Y INSERT INTO SAMPLE PORT AND PRESS <ENTER> KEY RESPIRATION FOLLOWS
12:15 CAL. 45 MIN

Syringe

- Insert the syringe into the sample port of the Combiline as shown in figure 5.
- **Inject sample slowly from syringe into sample port. Stop injection after the first acoustic signal**.
- Remove the Syringe after the second acoustic signal.

Capillary

- Insert the capillary into the sample port of the Combiline as shown in figure 5.
- Press ENTER key.
- The sample is aspirated automatically
- Remove the Capillary after the second acoustic signal.

The flow of the sample can be controlled as long as the Sensor Array is back-lighted. The process is controlled by a Light Barrier and a beep is heard when the filling is done. A second beep indicates that the syringe has to be removed.
When there is no detection of specimen by the Light Barrier, an automatic wash cycle starts and the STAND BY dialogue appears.
The following dialogue appears when the filling process is finished.

PREPARATION	
PLEASE REMOVE SAMPLE DEVICE	
12:18 CAL. 41 MIN	

- Remove the Sample device from the Sample Port.

CAUTION

Remaining of the syringe or capillary in the Sample Port will affect washing of the measuring capillary. Following measurements could be wrong!

The following dialogue appears automatically:

MEASUREMENT	QUIT
1130150310	ONLY BGA
TEMP 37.0	
HB 15.0	ONLY ISE
FIO2 20.9	
RQ 0.85	INPUTS
11:30 CAL. 41 MIN	

If you don't select anything out of this dialogue, the displayed patient data disappear after 20 sec and the measurement will start for all possible values.

Following selections can be made:
- ONLY BGA for the measurement of pO_2- and pCO_2-values.
- ONLY ISE for the measurement of electrolyte-values.
- INPUTS to enter patient specific data. Proceed as shown below.
- QUIT to terminate. Proceed as shown below.

NOTE

Type combiline BGA: by pressing of ONLY ISE, the pH-value will be measured only! (In case of no selection, all values will be measured pO_2, pCO_2, and pH).

Termination of a Measurement

QUIT: If you are intended to terminate the measurement, press the corresponding QUIT-key. The sample will be washed out. The STAND BY dialogue will then appear.

Input of Patient Data

During the first 20 sec after the MEASUREMENT dialogue is shown, it is possible to enter patient-specific data like:

- A patient ID number. The offered ID number consists of the current date and time and can be overwritten.

- The current patient temperature (Temp)
- The haemoglobin concentration (HB)
- The FIO_2 value (FIO_2) (Oxygen content of the inhaled air)
- The respiration quotient (RQ)

NOTE

- Proceed as follows:
- Press the corresponding **INPUT**-key.

Parameters that need no change can be confirmed or skipped by pressing the ENTER-key.

A colon appears behind the **patient number**.
- Enter the number desired by numerical keys (max. 8 figures).
- Change or confirm the number by pressing the ENTER-key.

A colon appears behind **TEMP**.
- Enter the current patient temperature and press ENTER-key to confirm.

A colon appears behind **HB**.*
- Enter the current Hb concentration and press ENTER-key to confirm. **(value is ignored when an active Hb-Sensor is present!)**

A colon appears behind **FIO_2**.*
- Enter the current FIO_2-value and press ENTER-key to confirm.

A colon appears behind **RQ**.*
- Enter the current RQ-value and press ENTER-key to confirm.

*** not available for Type Combiline ISE**

The INPUT dialogue disappears. The measurement process starts now. After approximately 45 sec the measured results are indicated and printed out automatically (see the following dialogue).

MEASUREMENT		QUIT	
PO2	90.0	HCO3	23.9
PCO2	39.0	HCO3S	24.2
PH	7.410	BE	0.3
K	4.5	SBE	0.1
NA	144	TCO2	24.9
CA	1.23	PB	48.3
CL	100	O2SAT	96.9
LI	0.45	O2CT	19.8
GLU	3.20	P50	26.55
LAC	2.55	AADO2	16.0
		A GAP	24.6
H+	41.0	SHUNT	4.4
CA 7.4	1.22		

During indication of results the sample will be washed out of the Sensor capillary and the STAND BY dialogue appears.

STAND BY		PROGRAM
PO2	= ACTIVE	
PCO2	= ACTIVE	
PH	= ACTIVE	
K	= ACTIVE	MEASURE
NA	= ACTIVE	
CA	= ACTIVE	
CL	= ACTIVE	
LI	= ACTIVE	QC
GLU	= ACTIVE	
LAC	= ACTIVE	
HB	= ACTIVE	RESPIRATION GAS
10:45	CAL. 40 MIN	

- Go as described above for the next sample.

3.1.1 Display and Print Results

The results of the sample measurements are stored on an integrated SD-Card. the results of 32000 measurements can be stored there.
To display the results proceed as follows:

- Press the PROGRAM key one time to get access to the OPERATION menue
- Press the **8** key to access the data memory
- The results of the last measurement will be displayed then.

1130150310		QUIT
PO2	90.0	
PCO2	39.0	
PH	7.410	PRINT
K	4.5	
NA	144	
CA	1.23	
CL	100	
LI	0.45	NEXT
GLU	3.20	
LAC	2.55	
HB	14.2	
H+	41.0	PREVIOUS
CA 7.4	1.22	547 548

actual number of totally stored results (547 of 548)

After selection of "**DISPLAY MEASURED VALUES**", first the measured values appear on the screen. For display of the calculated AB-Parameters, press the **ENTER** key.
Press **ENTER** key again to return the previous display of measure results.

- Press the corresponding PRINT-key for a print out.
- Press the corresponding QUIT-key to return to the STAND BY dialogue. (be done automatically after approx. 30 sec).
- Press the ENTER key to display the calculated AB-parameters

Remarks: A question mark "**?**" is shown if the max. measuring time was exceeded. For more details, refer to chapter **4 Error Messages**.

Lithium: value is "**--------**": value is out of range (<0.4 or >2.5)

```
ESCHWEILER COMBILINE II

NAME :

#                    1226250310

DATE   12:26  25.03.10
BP          760    mmHg
TEMP.      37.0    C
HB         14.2    g/0.1l
HCT        42.6    %
FIO2       20.9    %
RQ         0.85

PO2        90.0    mmHg
PCO2       39.0    mmHg
PH         7.410
H+         38.9    nmol/l
K          4.5     mmol/l
NA         144     mmol/l
CA         1.23    mmol/l
CA7.4      1.24    mmol/l
CL         100     mmol/l
LI         1.4     mmol/l
GLU         3.20   mmol/l
LAC        2.55    mmol/l

HCO3A      23.9    mmol/l
HCO3S      24.2    mmol/l
BE         0.8     mmol/l
SBE        0.1     mmol/l
TCO2       24.9    mmol/l
BB         48.3    mmol/l
O2SAT      96.9    %
O2CT       19.8    %
P50        26.55   mmHg
AADO2      16.0    mmHg
A GAP      24.6    mmol/l
SHUNT       4.4    %

ACID/BASE STATUS
NORMAL RANGE
**********
```

Patient ID number (#):
Date and Time
List of measured and calculated results

Figure 14 Print out of Results (example for combiline^{meta} BGA+E)

3.2 Accessories for capillaries

For combiline the following capillary size is required:

- capillaries 8 cm/100µl for analysers up to 3 test parameters
- capillaries 10 cm/125µl for analyser sup to 6 test parameters
- capillaries 12 cm/150µl for analysers up to 11 test parameters
- capillaries 14 cm/175µl for analysers with Hb up to 9 parameters
- capillaries 16 cm/200µl for all analysers with Hb up to 11 parameters

The capillaries are coated with ammonium-heparin [80 i.e/ml].

For a storage of filled capillaries, following additionals are available
- magnet stirrer for mixing of the specimen
- end-caps to close the capillary
- magnet to pull the stirrer out of the capillary

3.3 Quality Control Test

The **Q**uality **C**ontrol mode is used for the measuring of quality control solutions. In principle, all blood gas- or blood gas-electrolyte control solutions can be used according to the instructions of their manufacturers. Pay attention to country specific guidelines for quality control regulations.

The use of control materials makes it possible to evaluate the Combiline regarding the correctness and accuracy of the measuring results.

For input of Quality Control material from ampoules, the use of a special ESCHWEILER **Aspiration Pipe** (order no. 50 6 30 50) is necessary (see figure 15. Aspiration Pipes are included in the accessories of the Combiline.

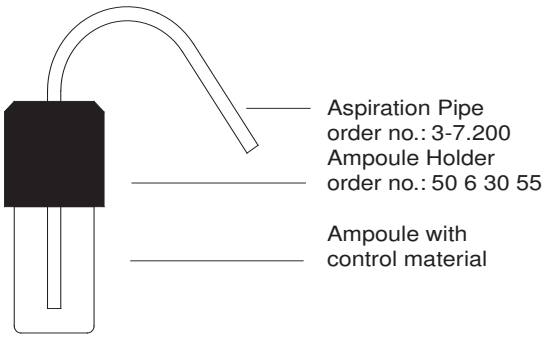


Figure 15 Aspiration Pipe

To introduce the control material proceed as follows:

- Keep ampoule holder and aspiration pipe ready.
- Before measuring, shake the ampoule for 10 seconds to mix the contents. Restore the control to the bottom of the ampoule by gentle tapping.
- Protect fingers with tissue paper or gloves to avoid injury. Snap the ampoule open.

CAUTION

Observe the suggestions in the package inserts for an exact use of the quality controls. Note that quality control material can be biological material!

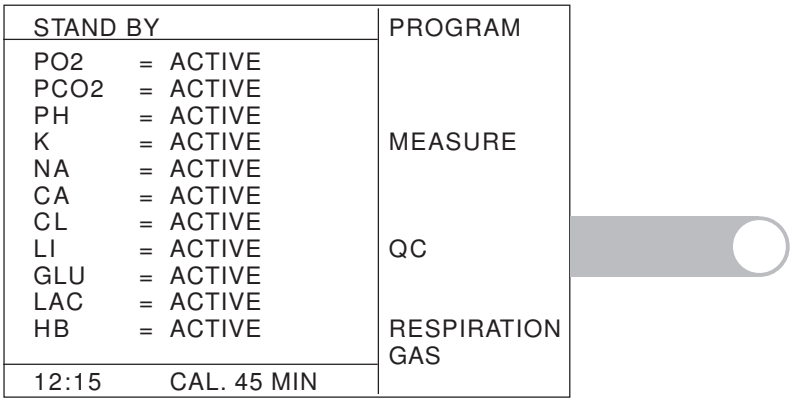
- Put the Aspiration Pipe with Ampoule Holder over the ampoule as shown in the figure 15 and immediately introduce the control into the analyser according to the following instruction.

CAUTION

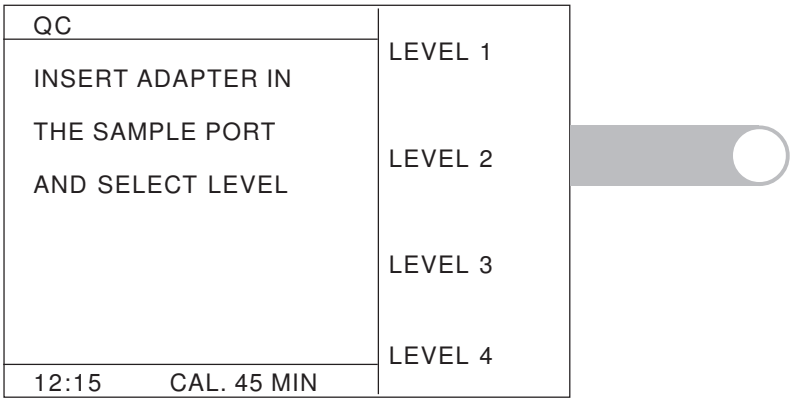
Blood-Gas control material should be sampled immediately after opening to avoid evaporation!

Test procedure

Proceed in principle as described in chapter **3.1 Using a Capillary** for a QC measurement.



- Press the corresponding **QC-key** and the following dialogue appears:



- Insert the **Aspiration Pipe** like a capillary into the Sample Port until the first resistant to adapt the metal canula.

Selection of a QC-level:

LEVEL 1 (acidosis)
LEVEL 2 (normal)
LEVEL 3 (alkalosis)
LEVEL 4 (high pO_2)

- Press the corresponding **LEVEL-key** to select the QC-Level.

The QC material is aspirated automatically out of the ampoule now.
- Follow the instruction as displayed in the dialogue.

A print-out of the results takes place automatically after completion of the measurement by integrated thermal printer.

- Make sure, that the QC results correspond to the expected range, otherwise start a calibration cycle and repeat the QC test.

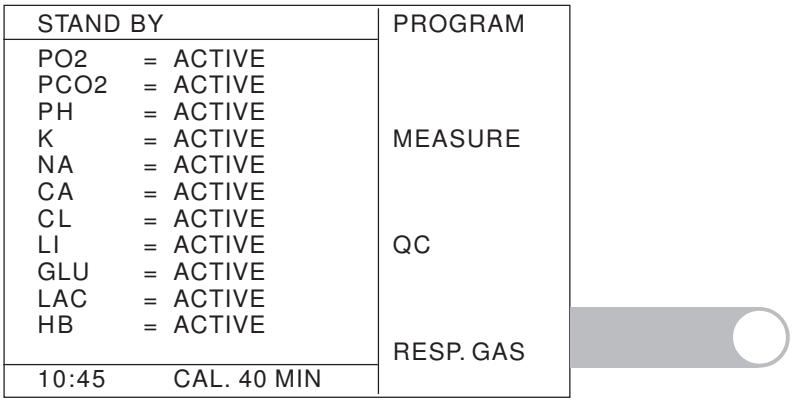
In case of failure:
- Print out Sensor Parameters and check them (s. chapter 3.5.1.6)
- Run Protein Removal cycle, (s. chapter 3.5.2.8)
- Call for Technical Service if the problem is still evident.

3.4 Respiration Gas

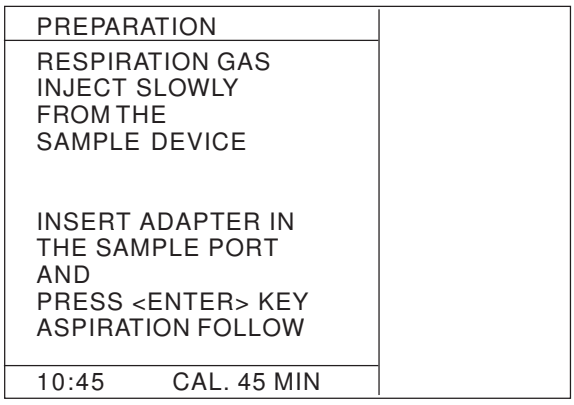
When the measurement option **RESPIRATION GAS** is selected, the parameter pO_2 and pCO_2 of the introduced gas-sample will be measured.

Respiration gas samples can be introduced directly like a capillary into the Sample Port from a **Glass Syringe** or from a **Douglas Pouch**.

Proceed in principle as described in chapter 3.1 Using a Capillary for a respiration gas measurement.



- Press the corresponding **RESPIRATION GAS** key and the following dialogue appears:



- Insert the **Syringe or Douglas Pounch** into the Sample Port

- Press the Gas out of the syringe or Douglas Pounch! The sample will be transported automatically into the Sensor's capillaries.
- Follow the instructions given in the dialogue.

A print-out of the results of pO_2 and pCO_2 takes place automatically after completion of the measurement by printer. The STAND BY dialogue appears than.

3.4.1 Urine

This function is available in combi*line* ISE only! It is used for measuring **K^+**, **Na^+** and **Cl^-** in urine samples. Urine measurements are made with syringes.

Preparation of urine samples:
Urine samples have to be diluted as follows:
- Pipette 0.9ml of urine-dilution solution (order no. 1-4.710) into a suitable vessel (e.g. Eppendorf-reaction vessel). To obtain a high as possible precision an automatic pipette should be used.
- Then pipette 0.1ml urine into the vessel.
- Close the reaction vessel and mix the content well.
- Fill the diluted sample into a 1ml or 2ml disposable syringe.

NOTE

Do not dilute urine samples by direct filling of urine and urine diluting solution into a syringe. Otherwise dilution mistakes may be caused.

The storage time of Urine samples should not exceed 24 hours. The samples should be kept at a cool place during the whole time of storage (refrigerator 4 °C). Due to decomposition products, measuring of older samples can cause damages of the ISE sensors.

- Press the corresponding **URINE** key and the following dialogue appears:

```
PLEASE WAIT FOR
SAMPLE INPUT
REQUEST
```

```
PREPARATION
URINE MEASUREMENT
USE DILUTION
S Y R I N G E
INJECT SAMPLE AND
WAIT TO REMOVE
SAMPLE DEVICE
C A P I L L A R Y
INSERT INTO
SAMPLE PORT AND
PRESS <ENTER> KEY
ASPIRATION FOLLOW
10:45        CAL. 45 MIN
```

- Insert sample device into the Sample Port
- Follow the instructions given in the dialogue.

A print-out of the results of **K^+**, **Na^+** and **Cl^-** takes place automatically after completion of the measurement by printer. The STAND BY dialogue appears than.

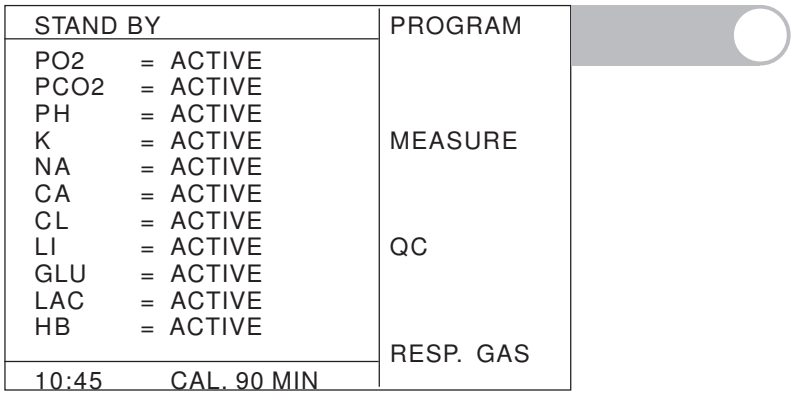
3.5 Operation Menus

The software offers different useful functions which can be selected by the operator.

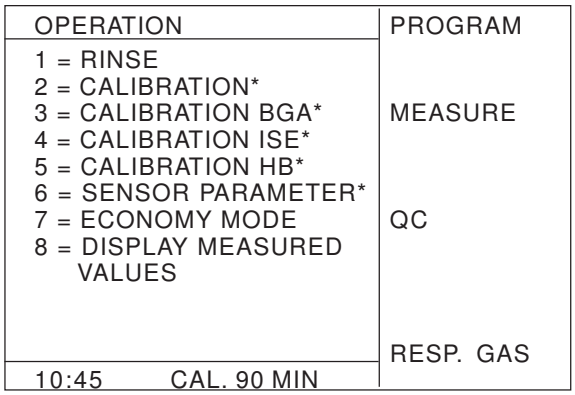
The menus can be selected by the corresponding PROGRAM-key, and functions can be selected by the numerical keys.

The functions are sorted into three submenus:
OPERATION, **SERVICE - TEST,** and **STANDARD DATA**.

Some functions can only be carried out when the Combiline is already warmed up. In the Software overview those functions are marked with a star "*" (see figure 13) and further descriptions!



If you press the corresponding **PROGRAM**-key **one time**, the **OPERATION** menu appears as shown below:



* not available during WARM UP

The menu functions listed in the dialogue can be selected by pressing the corresponding key on keypad.

Example: Press 1-key to carry out the RINSE-function or press 6-key to access the SENSOR PARAMETER listing.

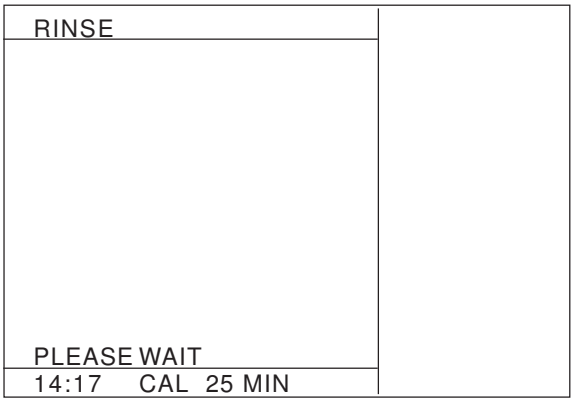
The dialogue will automatically return to STAND BY if no selection has been made within 60 secs or the corresp. QUIT-key has been pressed.

3.5.1 OPERATION Menu

To access the OPERATION Menu proceed as described in chapter 3.5. The purpose and the use of the functions are described in the chapters 3.5.1.1 up to 3.5.1.7 as follows. The function DISPLAY MEASURED VALUES is described in the chapter 3.1.1

3.5.1.1 Rinse

- Press the **1-**key to access the RINSE function, the following dialogue appears while rinsing:



Purpose

A manual start of the rinsing cycle can become necessary if sample leftovers are remaining in the measuring capillary after the automatic rinsing at the end of a measurement.

Carry out Rinsing

The rinsing cycle will be performed automatically with WASH Solution. While rinsing a backlight is on behind the measuring capillary and the valve compartment for a visual control.
The STAND BY or WARM UP PHASE dialogue appears when a rinsing cycle is performed.

3.5.1.2 Calibration

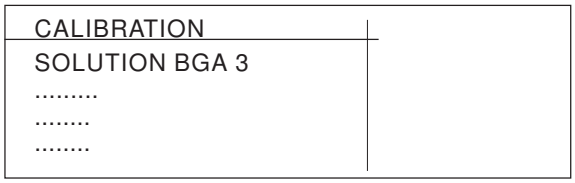
This function **cannot be performed** during **WARM UP PHASE!**
The Hb-Sensor must be activated separately (see chapter 3.5.1.5 Activation of Hb-Sensor)!

Purpose

A manual start of a 2-point calibration cycle. It can be necessary after
- Sensor maintenance
- installation of a new Sensor
- after any maintenance procedures

Carry out Calibration

- Press the **2-**key to perform a full Calibration, the following dialogue appears:



The lowest line always indicates the Solution which is currently in use.

All active Sensors are calibrated in the following sequence:

a. pCO_2-Sensor with BGA 1 / 3
b. pCO_2-Sensor with BGA 2 / 4
c, pH- and ISE-Sensors with CAL3
d. pH- and ISE-Sensors with CAL4 / CAL4+M
e. GLU and LAC Sensors with CAL4+M
e. pO_2-Sensor with AIR

Sensors that are marked with an error like e.g. SLOPE will also be calibrated. Error marks can only made disappear after a successful calibration cycle. Sensors that are inactivated (OFF) will not be calibrated.

The average length of time needed for a full calibration cycle is approx. 4-5 minutes. Type Combiline BGA or ISE: it takes only about 3 minutes.

During the calibration the voltage-values of the Sensors (or the current of the pO_2-Sensor) which are generated by the Calibration Solutions are stored in the internal memory.
The values of the Calibration Solutions, which are also stored in the internal memory, are assigned to the measured electrode signals.
Thus, when an unknown sample is measured, conclusions can be drawn on the basis of the electrode signals about the partial pressure values and ion concentrations present in the sample.

The STAND BY dialogue appears when the calibration process is performed. The countdown timer shows the time for the next automatic calibration process.

Cancellation

A manual started calibration process **cannot** be cancelled!

Calibration Error

If an error occurs during a calibration, status messages are shown in the dialogue.

Error messages which can appear after calibrations are:

- SLOPE (sensitivity of a Sensor)

The messages appear with designation of the corresponding Sensor.

For further information on calibration error, their avoidance and correction, see chapter 4 **Error messages.**

3.5.1.3 Calibration BGA

This function **cannot be performed** during **WARM UP PHASE!**
Not accessible for type Combiline ISE!

Purpose

A manual start of calibration for pO_2- and pCO_2-Sensors only. It can be necessary after
- pO_2/pCO_2-Sensor maintenance
- installation of a new pO_2- or pCO_2-Sensor

Carry out

- Press the **3-**key to perform the Calibration for pO_2- and pCO_2-Sensors only.

A dialogue appears indicating CALIBRATION for
SOLUTION BGA 1 / 3, SOLUTION BGA 2 / 4 and GAS.
When the calibration process is finished, the STAND BY dialogue appears. The time for the next automatic calibration is set to 90 MIN.
For further information refer to chapter 3.5.1.2.

3.5.1.4 Calibration ISE

This function **cannot be performed** during **WARM UP PHASE!**
Not accessible for type Combiline BGA!

Purpose

A manual start of calibration for ISE-Sensors only. It can be necessary
- after an ISE-Sensor maintenance
- after installation of any new ISE- or pH-Sensor
- after exchange of membrane shells of the concerned sensor

Carry out

- Press the **4-**key to perform the Calibration for ISE-Sensors.

A dialogue appears indicating CALIBRATION for
SOLUTION CAL3, SOLUTION CAL4 or CAL4+M.
When the calibration process is finished, the STAND BY dialogue appears. The time for the next automatic calibration is set to 90 MIN.
For further information refer to chapter 3.5.1.2.

3.5.1.5 Activation of Hb-Sensor

Function

Hb-Sensor activation can be carried out in STAND-BY mode only!

Activation

In order to maintain the measuring accuracy for determination of Hband to activate the Hb-sensor, an input of two factors HB-R and HB-T has to be carried out in STAND-BY mode

In case the COMBILINE was switched off for less than 24 hours

the Hb-factors are retained in the memory and the sensor remains ACTIVE.

In case the COMBILINE was switched off for more than 24 hours

The Hb-factors have to be entered as described below, the Hb-sensor is marked with OFF.

The mentioned Hb-factors are printed on a white flag at the Hb-sensor cable (see attached photo)

Carry out Hb-factor input

To activate the Hb-sensor:

- Press the **5**-key in OPERATION MENU to perform the Hb-calibration process, the following dialogue appears:

```
HB-SENSOR
HB R : 0.000
HB T :
```

- Enter the **HB-R value** given on the white ensign at the Hb-sensor by keypad e.g. 0.920 and press the Enter-key to confirm. The following dialogue appears:

```
HB-SENSOR
HB R :  0.920
HB T :  0.000
```

- Enter the **HB-T value** given on the white ensign at the Hb-sensor by keypad e.g. 0.592 and press the Enter-key to confirm.
- The **i**nput range for HB-R and HB-T is 0.300 to 2.000

For quality control of the Hb-Sensor, whole blood specimens whose Hb-concentration have already been determined with the help of suitable measuring methods may be used (e.g. oximeter).

Carry out Hb-Activation

HB - SENSOR		
HBR / HBT	0.970	0.517
MESS. [mV]	-1182	-320

printout of Hb-sensor parameter

HB/R = Reflexion factor
HB/T = Transmission factor
MESS = Hb-sensor voltages for Reflexion and Transmission measurement of the last sample measurement (in millivolt)

- **The use of Hb-calibration is not required anymore,** only the input of two parameters forrefexion and Transmission (HB-R and HB-T) is necessary.

- After setting the Combiline into operation, sensor related parameters have to be entered by keyboard. After that the Hb-sensor is active for measurement. These parameters (HB-R and HB-T) are printed on a white flag at the Hb-sensor cable.

NOTE

- **The sample volume required for a fully equipped Combiline BGA+E+HB is min. 210 - 240µl. The sample volume required for a combiline BGA+HB is approx. 160µl. So it is of particular relevance to use capillaries with adequate volume.**

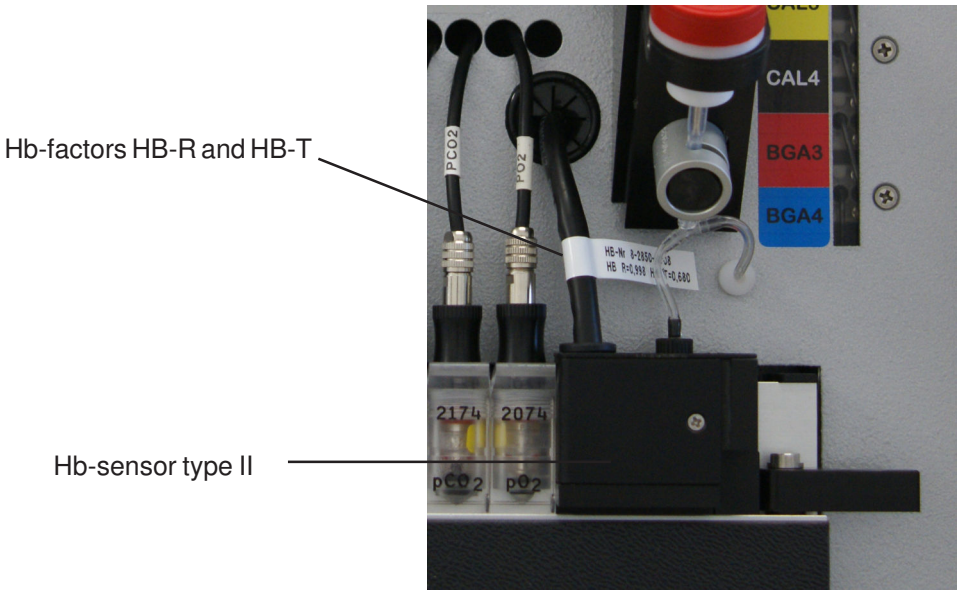
NOTE

- **Prerequisite for accurate and reproducible measurement of tHb is a sufficient heparinization of the whole blood sample with 60-80 IU / ml. Coagulation onset of the blood sample leads to false, in this case too low tHb measurement.**

- Please note that this measure method is suitable for measurement of whole-blood only! Quality controls are not usable!

- The measure range of the Hb-sensor is 3 - 30g/dl

- Hb will be measured if the sample light-barrier detects a whole-blood sample. Otherwise the programmed standard Hb-value is displayed (e.g. 15g/dl) and used for the calculation of the acid-base parameters. In case of too less sample volume, a “Transmission-voltage” of -4.000V is detected. The displayed Hb-value will be 0.0g/dl then. This can be observed on a sensor-parameter printout which can be made after a sample measurement (see sensor parameter printout)



Hb-sensor type II installed in combiline

3.5.1.6 Sensor Parameter

This function **cannot be performed** during **WARM UP PHASE!**

Purpose

The Sensor parameters give information about the current status "**condition**" of the Sensors. They are expressed in percent.
Check the Sensor parameters as described in the Maintenance schedule or in case of any malfunction.
Additionally the software revision number and the actual sample count is printed

Carry out Sensor parameters

- Press the **6**-key to display the Sensor parameters, the following display appears:

SENSOR PARAMETER		QUIT
O2	140	
CO2	70	
PH	99	PRINT
K	91	
NA	96	
CA	89	
CL	91	
LI	82	
GLU	127	
LAC	97	
15:47 CAL 25 MIN		

SLOPE in % (sensitivity of the Sensor)
It is computed from the difference between EC1 and EC2 (calibration voltage 1 + 2).

The **slope** of an electrode is a **measure for its sensitivity**. This results from the difference of the voltage values reached during a 2-point calibration.

The slope of the different Sensors must lie within the following ranges:

pO_2 : 75 - 230%
pCO_2 : 50 - 110%
pH : 86 - 110%
K^+ : 75 - 110%
Na^+ : 66 - 110%
Ca^{++} : 66 - 110%
Cl^- : 66 - 110%
Li^+ : 66 - 110%
GLU : 30 - 300%
LAC : 30 - 300%

If the slope of an electrode lies outside the given range, an appropriate message will be displayed.

If some or all Sensor parameters are out of the allowed range, check the transportation of all Calibration Solutions as described in chapter 3.5.2.9. (air-bubbles through leaks or stenoses)
If only some of the Sensor parameters are out of the allowed range,

- check if air bubbles are located inside of the ISE- or REF-Sensors, presupposed the transportation of Calibration Solutions is ok (refer to chapter 3.5.2.9 + 6.2).

- change the membrane of the indicated Sensors.

Print-out

More detailed Sensor parameter will be printed out by pressing the corresponding **PRINT**-key during indication of the Sensor-parameters.
On the print-out **slope values** and **high-level calibration voltages** of the last six calibrations are shown. This data give information about stability of the Sensors.


NOTE

In case of technical questions/problems concerning the Combiline it is recommended to send this data sheet to your Technical Service.

Excerpt from a Sensor parameter print-out

ESCHWEILER COMBILINE II SENSOR PARAMETER	
DATE 06:49 10.04.10	Time/Date of the printout
O2 - SENSOR	Sensor name
TIME SLOPE EC1 EC2	EC1- + EC2 = sensor voltages in mV
0629 140 -1660 -401	Time/Slope/EC1/EC2
MEAS. [mV] -380	EC1 = O2 Zero point voltage (fixed)
BGA L 0.0 mmHg	BGA L = O2 Zero point
BGA H 153.2 mmHg	BGA H = partial pressure of O2 in air
CO2 -SENSOR	next Sensor parameter
TIME SLOPE EC1 EC2	EC1- + EC2 = sensor voltages in mV
0629 74 1654 1772	Time/Slope/EC1/EC2
MEAS. [mV] 1815	
BGA L 62.5 mmHg	BGA L = "low" value (BGA1 / 3 pCO2)
BGA H 34.5 mmHg	BGA H = "high" value (BGA2 / 4 pCO2)
. . . .	
HB - SENSOR	
HBR / HBT 0.818 1.599	HB Activation Parameters
MEAS. [mV] -100 -1372	Refection and Transmission voltages of of last Hb measurement
SOFTWARE 2500	installed software version
COUNTER 3628	actual value **Sample Counter**

EC1 calibration voltage 1 (zero point) occurs at:

- Calibration with BGA 1 / 3 for the pCO_2-Sensor.
- Calibration with CAL 3 for ISE- and pH-Sensors.

EC2 Calibration voltage 2 occurs at:

- Calibration with BGA 2 / 4 for pCO_2-Sensors.
- Calibration with CAL4 or CAL 4+M for ISE- and pH-Sensors.
- Calibration with AIR for the pO_2-Sensor.

MEAS.

Sensor voltage of the last measurement.

BGA L

Concentration of low level calibration material referring to the values of pCO_2 of BGA 1 / 3.

BGA H

Concentration of high level calibration material referring to the values of pCO_2 of BGA 2 / 4.

3.5.1.7 Economy Mode

The Economy Mode serves for **saving reagents** in times of low operating rate of the Combiline.

In the Economy Mode calibrations are carried out in an interval of four hours only. While the Combiline is operated in the **Economy Mode,** measurements **cannot** be carried out directly.

Activation of Economy Mode

- Press the corresponding ECONOMY PROGRAM-key to activate the Economy Mode in STAND BY dialogue. The following dialogue appears:

ECONOMY MODE .... 14:17 CAL 240 MIN	QUIT

Inactivation of Economy Mode

- Pressing the corresponding QUIT-key, the Combiline returns to STAND-BY mode.

In Economy Mode, calibration cycles are prolonged from 90 to 240 minutes.

If you are leaving the Economy Mode the Combiline:
- carries out a calibration cycle if the last cycle has been finished more than 90 minutes ago.
- is at once ready for measurements if the last calibration cycle has been finished within 90 minutes.

3.5.2 SERVICE - TEST Menu

To access the SERVICE-TEST Menu proceed as described in chapter 3.5.
The purpose and the use of the functions are described in the chapters 3.5.2.1 up to 3.5.2.9 as follows.

SERVICE - TEST	OPERATION
1 = BGA 3 2 = BGA 4 3 = CAL3 4 = CAL4 5 = GAS 6 = AIR / TEMP 7 = LIGHT BARRIERS 8 = PROTEIN 9 = REAGENT TEST	START CALIBRAT.
10:45 CAL. 90 MIN	

3.5.2.1 Test pCO_2-Sensor voltage / BGA 1 / 3

Purpose

This function indicates the generated pCO_2-Sensor voltage (and pH voltage in Combiline BGA)after **calibration solution BGA 1 / 3** has been added. The voltages lie within a range of ± 3.5 V.

The programs give information about the behaviour of the pCO_2-Sensor (and pH sensor in Combiline BGA).
The indicated voltage should be stabilized within approx. 60 seconds. Differences of only small mV should be seen as normal (see chapter 3.5.2.3).
Otherwise
- check the transportation of the BGA 1/3 Calibration Solution (s. chapter 3.5.2.9) and the condition of the pCO_2-Sensor (s. chapter 3.5.1.6).

Reasons:
- Calibration Solution is not transported free of air-bubbles!
- Sensor membrane is dirty or defective.
- pCO_2- or pH-Sensor is worn out (inert)

Carry out test

- Press the **1**-key to display TEST BGA 1 / 3 dialogue:

TEST BGA 3	QUIT
E CO2 -1679 mV	

Refer to chapter 4.3 if the value is out of range!
- Press the **QUIT**-key to return to the STAND BY dialogue.

3.5.2.2 Test pCO_2-Sensor voltage / BGA 4

Proceed as described for BGA 1 / 3 chapter 3.5.2.1!
Difference: Supply of **BGA 2 / 4 calibration solution**.

3.5.2.3 Test pH-/ISE-Sensor Voltage/ CAL3

Purpose

The program gives information about the behaviour of the pH- and ISE Sensors. The function is not available in Combiline BGA.

This program indicates the generated Sensor voltages after **calibration solution CAL3** has been added. The voltages lie within a range of ±3.5 V.

The indicated voltages should be stabilized within approx. 60 seconds. If not:
- check the transportation of the corresponding Calibration Solution (s. chapter 3.5.2.9) and the condition of the corresponding Sensors (s. chapter 3.5.1.6).

Voltages over ± 3.5 V points to air-bubbles inside of the Ref-Sensor or to a defective membrane of the corresponding Sensor. Voltage fluctuations within ± 5 to 10 mV are normal and not relevant.

Carry out test

- Press the **3**-key to display TEST CAL3 dialogue:

TEST CAL3			QUIT
E PH	-136	mV	
E K	142	mV	
E NA	960	mV	
E CA	-537	mV	
E LI	1012	mV	
14:17 CAL 25 MIN			

Refer to chapter 4.5 and 4.6 if the values are out of range!
- Press the **QUIT**-key to return to the STAND BY dialogue.

3.5.2.4 Test pH-/ISE-Sensor Volt./ISE CAL4(+M)

Proceed as described for CAL3 chapter 3.5.2.3!
Difference: Supply of **CAL4 or CAL4+M calibration solution**

3.5.2.5 Test O_2-Sensor Voltage/Gas

Purpose

This program indicates the generated O_2-Sensor voltage after **air** has been added. The voltage usually lies between -500 and +100mV.
At a disconnected O_2-Sensor cable, the voltage must be:
-1700 mV ±50 mV.
This value is preadjusted by the manufacturer. It can in some instruments be at -1660mV. This variation is due to individual dynamic characteristics of the O_2 amplifier and O_2-sensors. If not, call for the Technical Service!
There is a danger of O_2-value deviation!

Carry out test

- Press the **5**-key to display TEST pO_2 GAS dialogue:

TEST PO2 GAS	QUIT
E O2 -162 V mV	
14:17 CAL 25 MIN	

Refer to chapter 4.4 if the value is out of range!
- Press the **QUIT**-key to return to the STAND BY dialogue.

3.5.2.6 Test Air Pressure and Temperature

Purpose

With this program the following parameters are indicated:
- Thermostat temperature, controlled at 37.0 °C ± 0.2
- Air pressure (BP barometric pressure) in [mmHg or kPa]

Thermostat temperature

The temperature of the thermostat is measured with a temperature Sensor which is located inside the metal block of the thermostat. The indicated temperature should be 37.0 °C +/- 0.2 °C. A Thermal protection-switch is also located at the rearside of the thermostat to avoid overheating.

Temperature deviations of more than 1 °C cause false values of the pO_2, pCO_2 and pH-Sensors! **Control the temperature every day**, because a temperature deviation is not controlled and indicated on display!

A temperature adjustment should only be done by the Technical Service!

Air pressure

The Combiline is equipped with an air-pressure Sensor which measures the current atmospheric air-pressure for the calibration of the pO_2 Sensor. Range: 500 - 900 mmHg (SI-units selection, see chapter 3.5.3.4).

The indicated air pressure should be compared with a reference barometer. If there is a deviation of more than ± 5 mmHg, call Technical Service.
A failure of the measured air-pressure leads to a Slope error of the pO_2-Sensor!

The pO_2-Sensor is calibrated by air. The current air-pressure is assigned to the measured O_2-value. The value is usually approximately 150 mmHg (on ocean level) (20.9 Vol% O_2) depending on air-pressure.
The normal air-pressure on ocean level is approx. 760 mmHg.

Reference Voltage

The reference voltage of the analog-digital converter is 2.048 V. The deviation must not exceed +/- 0.020 V. Otherwise measure results might be wrong.

Carry out test

- Press the **6**-key to display TEST AIR / TEMP dialogue:

```
TEST                              QUIT
EREF    2048      mV
TEMP     37.0     C
BP        744     mmHg
```

In case of deviations, call for Technical Service!
- Press the **QUIT**-key to return to the STAND BY dialogue.

3.5.2.7 Test Light Barriers

Purpose

This program serves for checking the sample detection Sensor (LB) at the end-point of the measuring capillary.
In case of any Light Barrier malfunction this function should be used first.

Possible indications:

Sample or Calibration Solution is not detected.

Carry out test

- Press the **7**-key to display the test dialogue:

```
TEST LB                    | QUIT
LB      2125      mV       |
                           | TEST
RINSING AFTER              |
QUIT OR 30 SEC             |
                           |
14:17   CAL   25 MIN       |
```

At first the Light-Barrier voltage for **AIR** is indicated.

- Press the corresponding **TEST**-key. WASH Solution will be sucked in automatically. The Light-Barrier voltage for watery solution is indicated then.

Ranges

Voltages of Correctly adjusted Light-Barriers should lie within the following ranges:
LB voltage for air: 1.600 - 2.500V
LB voltage for WASH: 0.200 - 0.500V

Call for Technical Service if the indications do not appear like described!
Sample light-barrier or its capillary need to be adjusted or exchanged.
For adjustment, or capillary replacement please note service manual.

Termination

- Press the **QUIT**-key to return to the STAND BY dialogue. This will be done automatically after 30 sec.

3.5.2.8 Protein Removal

This function **cannot be performed** during **WARM UP PHASE!**

Purpose

Depending on the sample throughput it is necessary to perform a cleaning of the analysis system with Protein Remover as recommended, refer to chapter 6.1 Maintenance Schedule.

To obtain high reproducibility of measure results and high stability of sensors, it is essential to use ESCHWEILER Protein Remover CLEAN1 (order no.: 5 6 10 80) at latest after performance of 100 tests or at least once a week!

Protein and Lipid sediments cause false voltages on Sensors and therefore false results!

Protein and Lipid sediments cause shortened life-time of membranes!

CAUTION

Carry out this program if the results of the Quality Control are out of range.

Carry out this program if the results of the Quality Control are out of range.

Carry out removal

For protein removal:

- fill a Syringe with about 1ml of **Protein Remover** (order no. 50 6 10 80). **Be careful**, Protein Remover is aggressive, wear suitable gloves! (Sodium-Hypochloride).

- Press the **8**-key to display the test dialogue:

- Proceed as displayed on dialogue:
- Insert the Syringe into the Sample Port.
- Inject Protein Remover slowly into the Sample-Port

- Remove the Syringe from the Sample Port as requested.

The Protein Remover remains in the analysis system for about 60 seconds. After that time the analyser performs two wash cycles and a calibration cycle automatically.

Termination

When there is no action within 30 sec, the STAND BY dialogue appears automatically.

3.5.2.9 Reagent Test (Test of Liquid Transport)

Purpose

With the help of this program the liquid pumps (roller pumps) and the valves can be activated manually.
In this way air bubbles which are trapped in the transport tubes can be removed and the function of pumps and valves can be tested.

This program should be used if you are intended to remove a Sensor out of the Sensor Array e.g. for maintenance purposes! **Hold this program activated as long as the liquid system is open!**

Use this program also for any other maintenance work at the liquid system e.g. for the replacement of Roller Pumps tubes.

Carry out test

- Press the **9**-key to display the test dialogue:

REAGENT TEST	QUIT
1 = SUCTION 2 = WASH 3 = BGA 3 4 = BGA 4 5 = CAL 3 6 = CAL 4 7 = GAS 8 = META	
10:45 CAL. 90 MIN	

VALVE in combiline ISE

- Press the corresponding numerical key to start the function desired. Every function will be performed as long as the numerical key is pressed.

Press QUIT-key to return to the STAND BY dialogue. Wash Solution will be sucked in automatically.

Function description

Abbreviation in parentheses ( ) indicates the functional part of the liquid system that must be activated and, therefor, can be therefore controlled by the operator or Technical Service by pressing the corresponding key.

SUCTION: liquid will be sucked out of the measuring capillary as long as the button is pressed. (SP, VE1, VE2, BL, VG)

WASH: Wash Solution will be transported through the meas.capillary as long as the button is pressed. (RP, BL, VG, VE1)

BGA 3: Calibr. Solution BGA 3 will be transported through the meas. capillary as long as the button is pressed. (RP, BL, VG, ABS, VE1)

BGA 4: Calibr. Solution BGA 4 will be transported through the meas. capillary as long as the button is pressed. (RP1, BL, VG, ABS, VE1)

CAL 3 Calibr. Solution CAL 3 will be transported through the meas. capillary as long as the button is pressed. (RP, BL, VG, ABS, VE1)

CAL 4: Calibr. Solution CAL 4 (+M) will be transported through the meas. capillary as long as the button is pressed. (RP1, BL, VG, ABS, VE1)

GAS: (VALVE) AIR will be transported through the meas. capillary as long as the button is pressed. (RP, VG, BL, ABS, VE1)

META: WASH2+M is transported through the metabolite sensors (RP1, RP2, BL, VG, ABS, VE1, META)

Abbreviation description:

RP = Roller Pump, SP = Suction pump, BL = back light, VG = valve array, ABS = ABS valve, VE1 = VE1 valve, VE2 = VE2 valve.

In case of liquid transport trouble check:
- liquid system about blockage or leaks
- sensor positioning and installation
- Sample Port if it's open
- Sensor Catch could be opened
- Positioning of Calibr. Solution Bags

3.5.3 STANDARD DATA Menu

To access the STANDARD DATA Menu proceed as described in chapter 3.5. The purpose and the use of the functions are described in the chapters 3.5.3.1 up to 3.5.3.7 as follows.

STANDARD DATA	PROGRAM
1 = CALIBRATION DATA 2 = DATE / TIME 3 = CORRELATION 4 = SETTINGS 5 = SENSOR SELECTION 6 = AB-PARAMETER	MEASURE QC RESPIRATION GAS
10:45 CAL. 90 MIN	

The Standard Data of the Combiline are stored in an internal memory buffered by a Lithium-Battery. This means that the Standard Data entered by the user are saved in the memory during brief power interruptions or if the analyser is switched off manually (s.chapter 1.2.4).

3.5.3.1 Calibration Data

Purpose

The values for pCO_2 of the Calibration Solution BGA 3 and 4 and the pCO_2 and pH of the calibration solution BGA1 and 2 can be different from Lot no to Lot no., therefore the parameter are not stored permanently. The dialogue for the Calibration data appears automatically if:
- the Calibration Solution Bag has been just replaced or
- the analyser has been switched off for more than 24 hours.

CAUTION

After every exchange of the Calibration Solution Bags an input or checkup of the calibration values becomes necessary. Use values printed on Bag's label!

Enter Calibration Data

- Press the **1**-key to display the dialogue:

```
CALIBRATION DATA
C O 2

BGA 3      : 71.5
BGA 4        31.0
```

Values for BGA 3: a colon appears behind BGA 3
(Not for Type Combiline ISE!)
- Enter the pCO_2-value e.g. 71.5 printed on the Calibration Bag BGA 3 (red) by numerical keys and press ENTER-key to confirm.

Values for BGA 4: a colon appears now behind BGA 4
(Not for Type Combiline ISE!)
- Enter the pCO_2-value e.g. 31.0 printed on the calibration bag BGA 4 (blue) by numerical keys and press ENTER-key to confirm.

The entered calibration values are stored in internal memory.
The Combiline now performs automatically a calibration cycle (except in WARM UP PHASE).

The STAND BY dialogue appears for further actions.

NOTE

Type COMBILINE BGA: additional request for the input of the pH-values. See Calibr.-Bags BGA 1 + BGA 2.

3.5.3.2 Date and Time

With this function Time and Date, which are blended in at the bottom line of the display, are set. Date and Time are generated by a battery-operated real-time clock and continue running when the Combiline is out of operation.

Purpose

A change can be necessary if:
- there is a change in summer and wintertime
- after a service action e.g. a battery exchange.

Carry out function

- Press 2-key to display the Date and Time dialogue:

```
DATE / TIME
DAY    : 27
MONTH  : 02
YEAR   : 10
HOUR   : 14
MINUTE : 22

14: 20   CAL 16 MIN
```

Note: Values that need no correction can be skipped or confirmed by pressing the ENTER-key

A colon appears behind **DAY.**
- Enter the day by the **numerical keys** and press **ENTER**-key to confirm.
- The colon now appears behind **MONTH**. The input has to be made as described above.

The new Date and Time is stored in the memory.
The Time is indicated on the display. Date and Time are printed out together with measured values, Sensor parameters, and status print-out.

3.5.3.3 Correlation

Purpose

Setting of Correlation factors. This dialogue can be used if you are intended to bring the COMBILINE into line with another analyser. **You have to compute the correlation factors by yourself!**

Carry out function

- Press 3-key to display the Correlation factor dialogue:

```
CORRELATION
PO2        : 1.000
PCO2         1.000
PH           0.000
K            1.000
NA           1.000
CA           1.000
CL           1.000
LI           1.000
HB           1.000

14:17   CAL   25 MIN
```

Parameter range:
pH ± 0.050
all other: 0.800 to 1.200 ± 20%

- Enter the factor behind the colon and press ENTER-key to confirm.

Note for pH-factor

If a correlation factor is entered, press the ENTER-key to confirm. PLUS and MINUS will appear. The entered value will be added or subtracted from the result.
- Press corresponding key for setting of PLUS or MINUS (addition or subtraction).

3.5.3.4 Settings

Purpose

The standard values of **Hb, FIO2 and RQ** are preset to the following values:

Pre-settings		Range
Hb	= 15.0g/dl	0.0 - 30.0g/dl
FIO2	= 20.9%	15.0 - 100.0%
RQ	= 0.85	0.70 - 1.00
PRINTOUT	= 1	1 to 4 printouts (factor)

Carry out function

- Press **4**-key to display the Settings dialogue:

SETTINGS	
PRINTOUTS 1	
HB	:15.0
FIO2	20.9
RQ	0.85
GAS	mmHg
META	mmol/l
14:17 CAL 25 MIN	

Note: Settings that need no change can be skipped or confirmed by pressing the ENTER-key.

A colon appears behind **HB**.
- Enter the desired **Hb**-value by numerical keys and press **ENTER**-key to confirm. **If an Hb-Sensor is installed**, the Hb-value will be used only if the Hb-Sensor is inactivated or SLOPE is indicated.

A colon appears behind **FIO2**.
- Enter the desired **FIO_2**-value by numerical keys and press **ENTER**-key to confirm.

A colon appears behind **RQ**.
- Enter the desired **RQ**-value by numerical keys and press **ENTER**-key to confirm.

A colon appears behind **PRINTOUTS**
- Enter the desired number of print outs by **numerical keys** and press **ENTER**-key to confirm. (Every print out will be copied x-times)

A colon appears behind **UNIT GAS**
- Select the desired unit for pO_2, pCO_2, P50, $AADO_2$, and barometric-pressure by corresponding key between **mmHg** or **KPa.**

The new standard values are now stored and taken into account in all following sample measurements.

3.5.3.5 Sensor Selection

Purpose

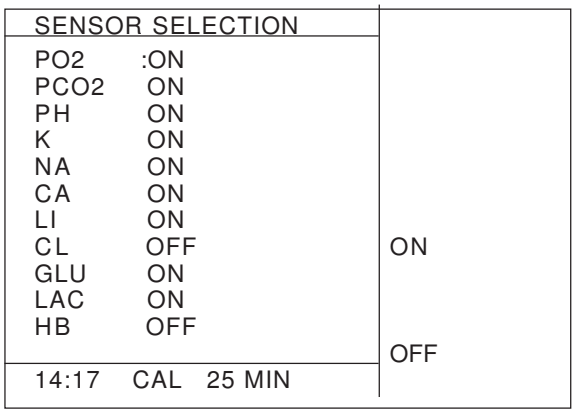
With this menu individual Sensors can be activated or inactivated according to the user's need or in case of a Sensor malfunction. After replacement of a defective Sensor the new one can be activated in this dialogue.

ON : The Sensor is active. It takes part in the measurements and calibrations. (ON = activated in STAND BY dialogue).

OFF: The Sensor is inactive. It does not take part in the measurements and is not calibrated either. (OFF = inactivated in STAND BY dialogue)

Carry out selection

- Press 6-key to display the dialogue:



A colon appears behind **PO2**.
To **inactivate** a Sensor, press the corresponding OFF-key**.**
To **activate** a Sensor, press the corresponding ON-key.

The colon appears behind the next Sensor now, go o as described.

In case of a **Sensor activation**, a calibration of all Sensors is performed automatically.

The STAND BY dialogue appears after the last confirmation.

3.5.3.6 AB-Parameter Selection

Purpose

The AB-parameter (acid-base) calculated from measured- and entered values are printed out only if the measurement is finished.
With the program AB-PARAMETER, the expression of unneeded acid-base parameter can be inhibited. Parameter that had already been excluded from expression can be switched on again.

ON - Parameter are expressed
OFF - Parameter are not expressed

Carry out selection

- Press the **7**-key to display the AB-parameter dialogue:

AB-PARAMETER		
HCO3A	: OFF	
HCO3S	ON	
BE	ON	
SBE	ON	
TCO2	ON	
BB	ON	
O2SAT	ON	
O2CT	ON	
P50	ON	ON
AADO2	ON	
AGAP	ON	
SHUNT	ON	OFF
SB-STATUS	ON	

A colon appears behind **HCO3A**.
To **inactivate** a calculation, press the corresponding OFF-key**.**
To **activate** a calculation, press the corresponding ON-key.
The colon appears behind the next parameter.
The selection is made for all parameter as described above.
The STAND BY dialogue appears after the last confirmation.

3.7 Replacements

3.7.1 Calibration Solution

If an empty Calibration Solution Bag needs to be replaced, that will be indicated on display e.g.:

BGA 3	QUIT
PLEASE CHECK.	

A similar message appears if any other bag is empty.

Check if the bag is really empty, otherwise the transportation way could be disturbed e.g. the Sample Port is open! If necessary, check the transportation of liquids as described in chapter 3.5.2.9!

Replacement

Proceed as follows for the replacement of BGA 3 as example:

- Press and hold the Slide Bar (**A**) for BGA 3 to open the access to the corresponding metal canula (see figure 15/installation).
- Remove the empty bag and release the Slide Bar BGA 3. A light barrier signal will be sent than to the controller.
- Take a new Calibration Solution Bag which is to be replaced.
- Press and hold the Slide Bar (**A**) for BGA 3.
- Press the Septum (**B**) of the new bag against a small resistant over the metal canula.
- Release the Slide Bar BGA 3. The Septum is now fixed by the Slide Bar. The Calibration Solution will be sucked in automatically.

The dialogue CALIBRATION DATA appears automatically to control or change the calibration parameter (only for BGA 3 + BGA 4). Proceed as described in chapter 3.5.3.1.

For the replacement of CAL3 + CAL4+M just unscrew the empty bottle from the connecting cap and remove the empty bottle from the support area. Then install a new bottle, put the feeding tube into the new bottle and screw the cap on again. Then place the new bottle in the support area.

3.7.2 Wash Solution

When the Wash Solution Bottle is empty, the analyser permits no further measurements or calibrations and the following message will be displayed:

WASH SOLUTION	QUIT
PLEASE CHECK.	

Check if the bottle is really empty, otherwise the transportation way could be disturbed If necessary, check the transportation of liquids as described in chapter 3.5.2.9!

For a replacement proceed as follows:

- Pull out the empty Wash Solution Bottle and take a new one.

- Unscrew the cap. The cap might be used later to close the full Waste Bottle after its replacement. The Wash bottle is closed by an aluminium film.
- Cut the aluminium film crosswise with a scalpel and push it into the bottle.
- Lift the Wash Bottle Adapter equipped with a long plastic tube.
- Insert the tube into the Wash Solution Bottle and put the Adapter over the Bottle (see figure 14).
- Press the corresponding **QUIT**-key to confirm the replacement.

3.7.2.1 CAL3 / CAL4 (+M)

When the CAL3 or CAL4 Bottle is empty, the analyser permits no further measurements or calibrations and the following message will be displayed:

CAL3 SOLUTION	QUIT
PLEASE CHECK.	

Check if the bottle is really empty, otherwise the transportation way could be disturbed! If necessary, check the transportation of liquids as described in chapter 3.5.2.9!

For a replacement proceed as follows:

- Pull out the empty Bottle and take a new one.
- Cut the aluminium film crosswise with a scalpel and push it into the bottle.
- Lift the CAL3 Bottle Adapter equipped with a long plastic tube.
- Insert the tube into the Wash Solution Bottle and put the Adapter over the Bottle.
- Press the corresponding **QUIT**-key to confirm the replacement

3.7.3 Waste Solution

After measurement, the specimens are collected in the Waste Bottle together with Calibration- and Wash Solutions. The filling level of the Waste Bottle is controlled by a Level Sensor. When the maximum permissible filling level is reached, the analyser permits no further measurements or calibrations.

When the Waste Solution Bottle needs to be replaced, that will be indicated on display:


Biohazard

WASTE BOTTLE	QUIT
PLEASE CHECK.	

For a replacement proceed as follows:

- **Wear gloves** for your own safety!
- Pull out the Waste Solution Bottle. **Be careful there is a risk of infection!** Pull bottle together with cap out of the position, angle both slightly up. Hold cap and pull the bottle downwards out of the cap.

- Clean the cap with a lint-free cloth and a suitable **disinfection solution** as recommended in chapter **! 2 Maintenance and Hygiene.**

- Dispose the Waste Solution in compliance with the legislations.
- Replace the full Waste Bottle with an empty Wash Solution Bottle.
- Press the corresponding **QUIT**-key to confirm the replacement.

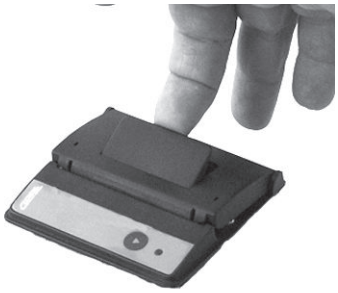
3.7.4 Printer Paper

The printer's thermal paper (order no. 50 5 50 00) is located on the upper side of the Combiline under a covered paper box. A red stripe on the print-out indicates that the paper supply is only sufficient for a few more print-outs.

Paper specifications:

Roll-diameter: up to 60mm
Roll-width: 57mm
Paper thickness: 0.04mm

To replace a roll of thermal paper, proceed as shown in below figures:



- open paper box and take out remaining paper

- put new paper roll into the paper box and pull out some paper, then close paper box

4 Error Messages

4.1 Error Eleminations

When an error message is indicated on dialogue:
1. the cause must be basically solved.

2. The error messages can be eliminated by carrying out a calibration cycle. This applies only if the cause of the error has first been eliminated.

4.2 Error Indications

The analyser's functions are controlled permanently by the internal processor. Any malfunctions are reported to the user by display.

STAND BY	PROGRAM
PCO2 SLOPE	MEASURE
	QC
	RESPIRATION GAS
14:17 CAL 25 MIN	

The meanings of the abbreviations used are described on the following pages.

NOTE

Sensors for which an error message is shown supply no measuring results during a sample measurement.

In case of failure of the pO_2-Sensor, the parameters O_2SAT, O_2-CT, p50, and $AADO_2$ are not calculated.

In case of failure of the pCO_2- or pH-Sensor the acid-base parameters HCO_3A, HCO_3S, BE, SBE, TCO_2, and PB, and the SB-status are not calculated.

If an error message is indicated for all Sensors, the Combiline permits no further sample measurements.

Error Messages

Error Message: **SLOPE** appears instead of ACTIVE for a Sensor like: ISE-, BGA-, and Metabolite-Sensors after a calibration cycle.

Cause: Sensor's slope is out of range because:
- Sensor Membrane is defect
- Sensor unit is defect
- air bubbles in Calibration Solution cover more or less the concerned Sensor

- especially for pH- and ISE-Sensors: possible disturbance of the Ref.-Sensor. Call Tech. Service!

Remedy: Proceed in the following order:

- call up the REAGENT TEST menu (s. chapter 3.5.2.9) and check visually all Solutions about air-bubbles. If air-bubbles present in a solution, press the corresponding button to rinse them out. If air-bubbles are still evident, call Technical Service to solve it.
- Run a manual Calibration cycle (s. chap. 3.5.1.2). If SLOPE is indicated furthermore, go to the next step.
- Replace the Sensor-Membrane of the indicated Sensor (s. chapter 5.2). The problem should be solved now. If not, call Technical Service.

In the following chapters 4.3, 4.4, 4.5, and 4.6 special diagrams are shown to solve indicated SLOPE errors. Proceed as necessary.

Message: "?" is indicated with a result on display as long as the measure procedure is going on.
It is indicated on the printout in case the pernissible time for measurement has been exceede by the sensor. In that case it will remain on the display as well.

Cause:

- Air-bubbles in sample are still located at a Sensor
- Owing to sedimentations on the Sensor or the Sensor is slowly worn out, the Sensor becomes inert.
- Concentration or partial pressure is out of range.
- Sensor-Membrane is worn out or defective.

Remedy: Proceed in the following order:

- Make sure that samples don't contain air-bubbles.
- Run a Protein removal cycle (s. chapter 3.5.2.8)

If the "**?**"-mark is still present, check the corresponding Sensor of it's indolence:

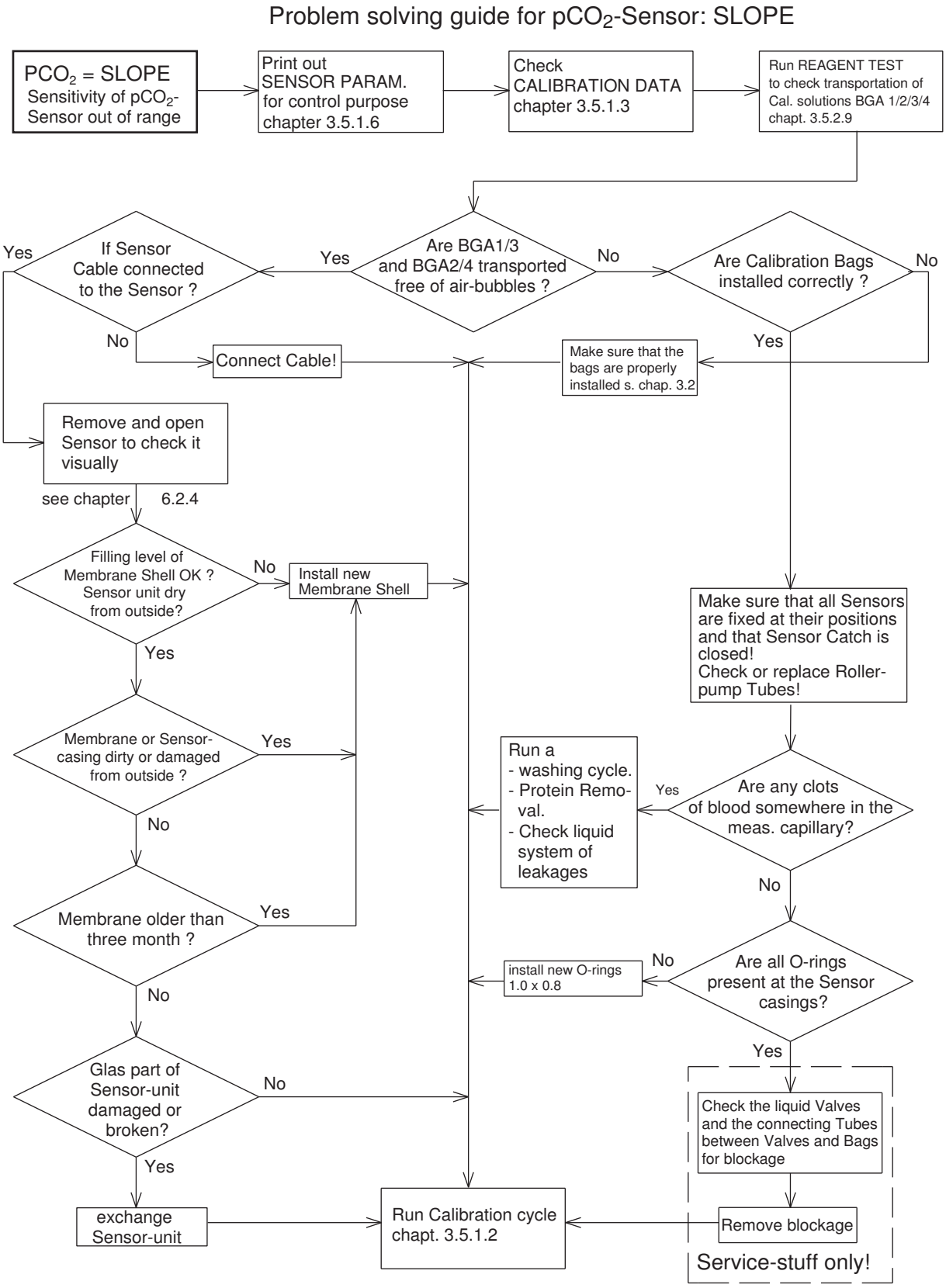
- Check the Sensor indolence as described in the corresponding chapters 3.5.2.1 to 3.5.2.4.

The pCO_2-Sensor can be checked with TEST BGA 3 and BGA 4. The pH- and Ref.-Sensor can be checked with TEST CAL3 and CAL4+M.

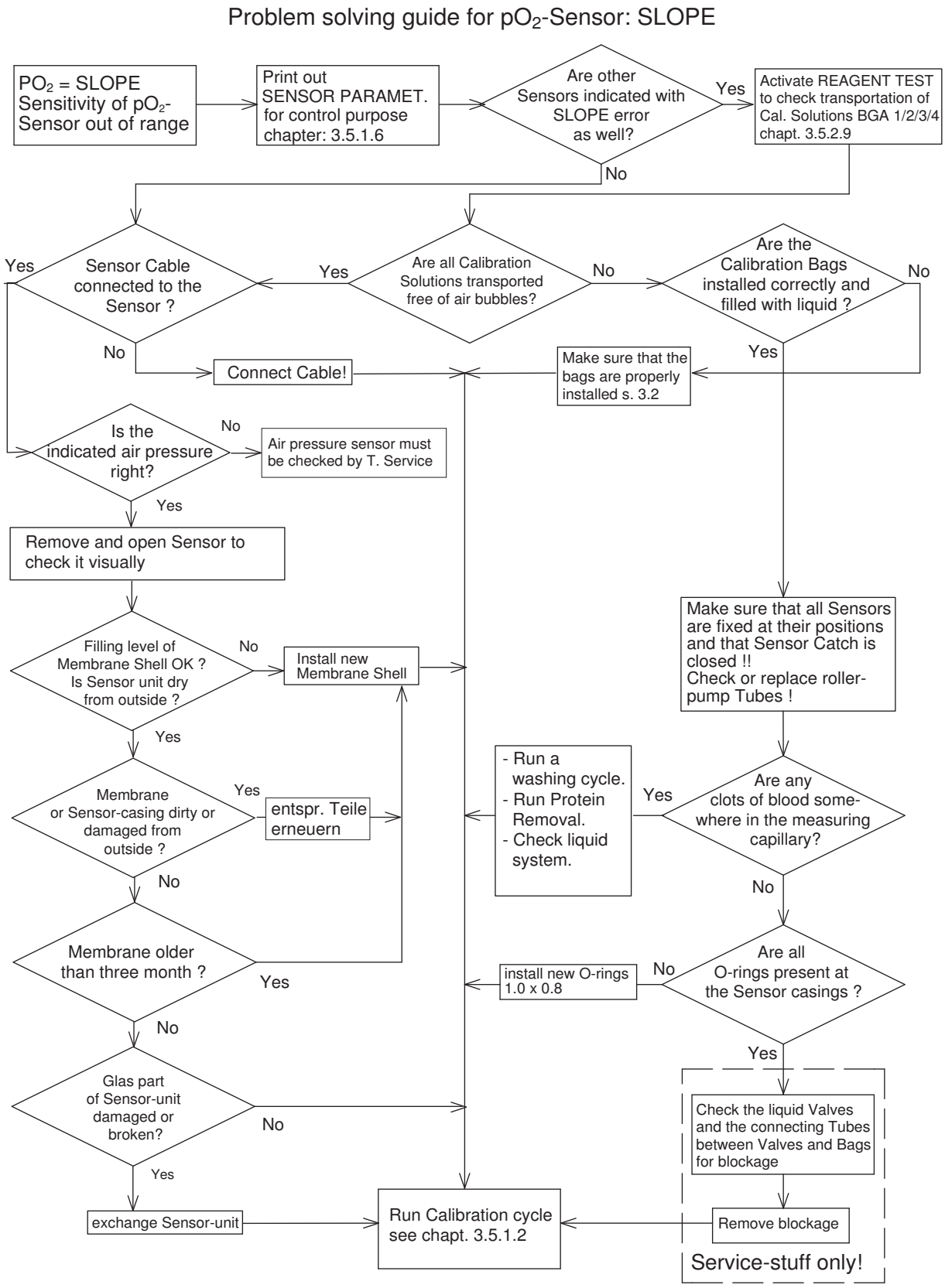
The indicated voltages should be stabilised within 30 to 60 seconds. After that, tolerance of ± 5 to 10 mV is normal. If the Sensor is not stabilised:

- replace the Membrane of the corresponding Sensor.

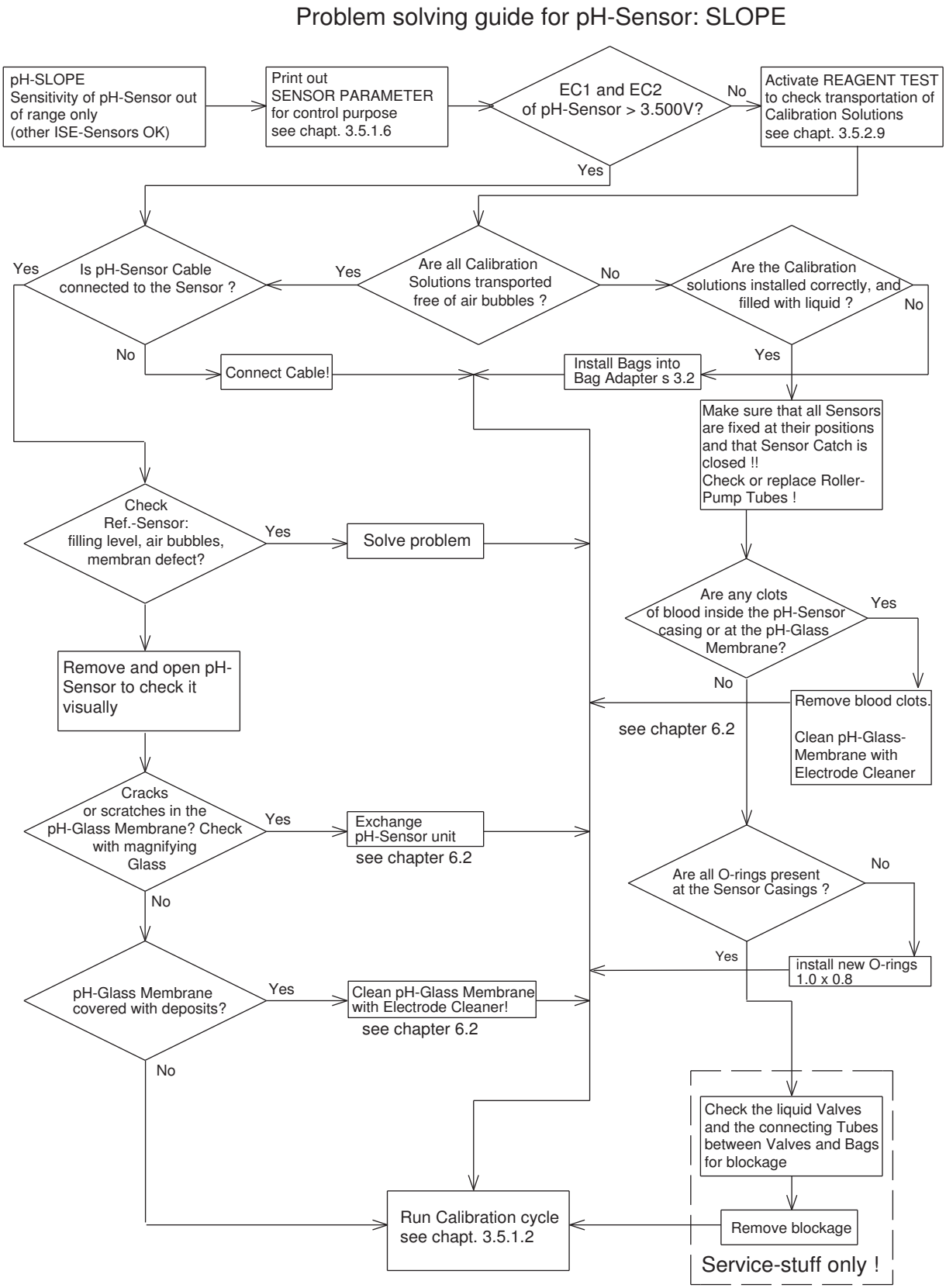
4.3 pCO_2-Slope Error



4.4 pO_2-Slope Error

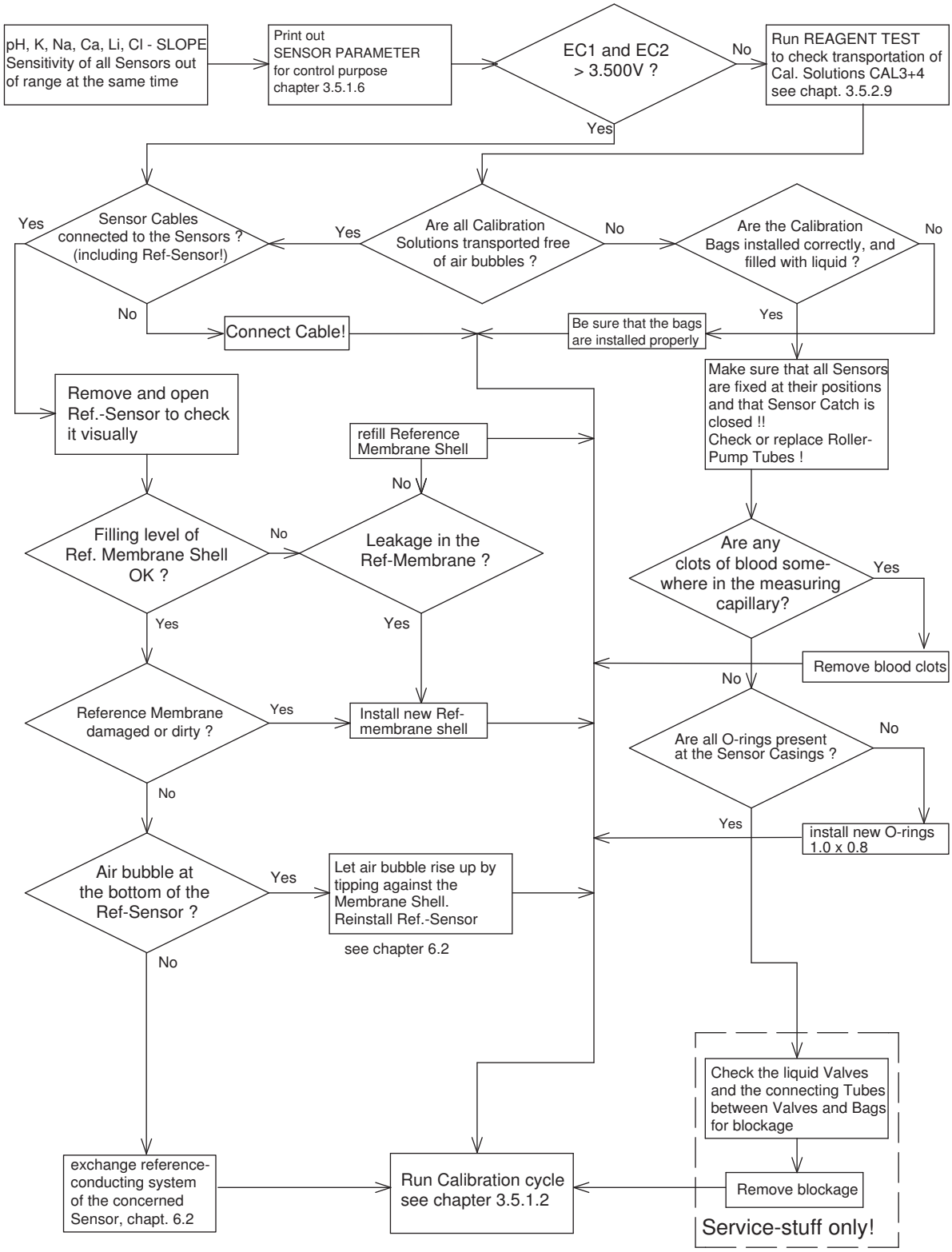


4.5 pH-Slope Error



4.6 ISE-Slope Error

Problem solving guide for pH- and electrolyte-Sensors: SLOPE



5 Explanation of Testparameter

5.1 Entered Values

Following test parameters are pre-defined in menu STANDARD DATA/ SETTINGS for result reports.

Hb Haemoglobin concentration in whole blood

A standard haemoglobin concentration of 15g/dl is prescribed. If the Hb-concentration of a patient deviates from this value, the individual Hb concentration of the patient can be entered by keyboard after initiation of the measurement. (This step is not necessary for analysers with the Hb-measurement option).

The standard haemoglobin concentration which is valid for every measurement can be set between 0.0 and 30.0 g/dl in the menu STANDARD-DATA/SETTINGS.

If the Hb-Sensor is installed the pre-defined Hb-parameter is only used if the Hb-Sensor is inactivated or SLOPE is indicated.

FIO_2 Oxygen content of the inhaled air in vol. %

A standard FIO_2-value of 20.9% (oxygen content of the atmosphere) is prescribed by the analyser. The standard value can be set in the menu STANDARD-DATA/SETTINGS and is then valid for all following measurements.

To measure samples taken from patients under artificial respiration, the individually used oxygen content of the respiration air (FIO_2) can be entered during the measurement. The input range includes an O_2-content of 15-100%.

RQ Respiration quotient

The respiration quotient gives the relationship between CO_2 produced and O_2 consumed. A standard value of 0.85 is set in the equipment. This value can be changed during a measurement between 0.70 and 1.00 if the RQ has been, for example, determined with a respirometer.
The standard RQ can be changed in the menu STANDARD-DATA / SETTINGS.

TEMP Patient temperature

If no other entry is made, the measured values for pO_2, pCO_2, and pH are output for a patient temperature of 37.0 °C. If the temperature of a patient deviates from this value after the sample is taken, the current temperature can be entered during the measurement by keyboard. The measuring results are then automatically converted into the temperature entered.

Influence of the manual entered temperature value

The measured pO_2-, pCO_2- and pH-values will be corrected in dependence of the entered temperature.
Temperature is
- increasing: pO_2-, pCO_2-values increase, pH-value decrease
- decreasing: pO_2-, pCO_2-values decrease, pH-value increase

5.2 Measured Parameters

BP (barometric pressure)

Air pressure BP

The current air pressure is measured continuously by an integrated air pressure Sensor. The values for pO_2 and pCO_2 depend on the current air pressure. This has to be taken into account when the electrodes are calibrated. For the measurements the measured air pressure at the time of the calibration is taken into consideration.

pO_2

Partial pressure of the oxygen in mmHg or kPa. Measuring range: 0-800 mmHg or 0- 107 kPa.

pCO_2

Partial pressure of carbon dioxide in mmHg or kPa. Parameter for respiratory component of the acid-base balance.
Measuring range: 5-200 mmHg or 0.66 - 26.6 kPa.

NOTE

In the menu STANDARD-DATA an expression of the values for pO_2, pCO_2, and BP in mmHg or kPa can be selected.

pH

Measuring unit for the current **hydrogen ion concentration**. Measuring range: 6.0 - 8.0

Electrolytes

K^+

Potassium ion concentration
Measuring range: 0.0 - 20 mmol/l

Na^+

Sodium ion concentration
Measuring range: 20 - 250 mmol/l

CA^{++}

Calcium ion concentration
Measuring range: 0.0 - 5.0 mmol/l

Ca 7.4 (calculated)

Calcium ion concentration computed for a pH-value of 7.4

Li^+

Lithium ion concentration
Measuring range: 0.40 - 5.0 mmol/l

Cl^-

Chloride ion concentration
Measuring range: 20 - 250 mmol/l

Metabolites

GLU

concentration of glucose in mmol/l or mg/dl

LAC

concentration of lactate in mmol/l or mg/dl

Haemoglobin

Hb

total haemoglobin
The tHb is the sum of all Hb-derivatives and is expressed in g/dl. Measuring range: 3 - 30 g/dl.

Parameter overview

The following table shows the units and ranges off all parameters measured in a fully equipped Combiline.

The reference values refer to K. Dörner, *Klinische Chemie und Haematology*, Enke Verlag Stuttgart, 3. Auflage 1999

Parameter	Unit	Measure-Range	Reference-Range
pO_2	mmHg	0 - 800	65 - 100
	kPa	0 - 107	8.66 - 13.33
pCO_2	mmHg	5 - 200	35 - 48 male 32 - 45 female
	kPa	0.66 - 26.6	4.66 - 6.4 male 4.26 - 6.0 female
pH		6.0 - 8.0	7.36 - 7.44
K^+	mmol/l	0.0 - 20.0	3.5 - 5.1
Na^+	mmol/l	20 - 250	135 - 145
Ca^{++}	mmol/l	0.0 - 5.0	1.12 - 1.32
Cl^-	mmol/l	20 - 250	97 - 100
Li^+	mmol/l	0.40 - 5.0	-
GLU	mmol/l	0.0 - 30	
	mg/dl	0.0 - 545	
LAC (-L)	mmol/l	0.0 - 20	
	mg/dl	4.5 - 180	
tHb	g/dl	3 - 30	13.3 - 17.7 male 11.7 - 15.7 female
Baro. pressure	mmHg	500 - 900	-
	kPa	66.7 - 120	

Table 2 Reference values for adults

The above listed reference values refer to adults, for new born babies and children, values can be different. Detailed information is given in the above mentioned literature and chapter 7.8.

5.3 Calculated Parameter

HCO_3-A
Actual plasma bicarbonate concentration
Parameter for the non-respiratory component of the acid-base-balance which, however, is influenced by the lung function.
Range: 10 to 50 mmol/l.

HCO_3-S Standard bicarbonate concentration
Parameter for the non-respiratory component of the acid-base-balance. Bicarbonate concentration in plasma at a pCO_2 of 40 mmHg, a temperature of 37 °C, and complete oxygen saturation of the haemoglobin.
Range: 10 to 50 mmol/l

BE Base excess
BE is defined as the bicarbonate amount above (+) or below (-) the normal content (0 mmol/l) of buffer base and depends on the Hb-concentrations entered and the measured pH- and pCO_2-values.
Range: -25 to +25 mmol/l

SBE Standard base excess
SBE is defined as the bicarbonate amount above (+) or below (-) the normal content (0 mmol/l) of buffer base. Calculation is made from the measured pH- and pCO_2-values, and an Hb-concentration of 6 g/0.1 l.
Range: -25 to +25 mmol/l

TCO_2
Total carbon dioxide
TCO_2 indicates the sum of the bicarbonate concentration and the physically dissolved carbon dioxides in the plasma.
Range: 10 to 50 mmol/l

BB Buffer bases
BB shows the sum of all buffer anion concentrations in the blood (haemoglobin, bicarbonate, protein, phosphate). Range: 0 to 100 mmol/l

O_2SAT Oxygen saturation of the haemoglobin
The oxygen saturation shows the percentage of possible bonding points of the haemoglobin which are occupied by oxygen. O_2SAT is independent of the Hb-concentration. Range: 20 to 100%

O_2CT Oxygen concentration
O_2CT is the sum of physically dissolved and chemically bonded oxygen and is mainly determined by pO_2 and Hb. Range: 0 to 40%

p50 Semi-saturation pressure
The semi-saturation pressure p50 shows the oxygen partial pressure at which the haemoglobin is 50% loaded with oxygen.
Range: 10 to 50 nmmHg

$AaDO_2$ Alveolararterial oxygen pressure difference
The $AaDO_2$-parameter is defined as the difference of the oxygen content between the alveolar air and the arterial blood (measured pO_2).
Range: 0 to 800 mmHg

HCT Haematocrit

Haematocrit is defined as the percentage of red blood cells to the total blood volume. Range: 0 to 100%. Only in connection with an Hb-measurement.

H+ Hydrogen ion concentration

Calculated from the measured pH. Range: 10 - 1000 nmol/l

SHUNT

Fraction of venous blood which is not oxygenated while paassing through alveoli in the lung

A-GAP

Concentration difference between measured cations Na^+ and K^+ and the anions Cl^- and HCO_3^-A

AGAP=$(Na^+ + K^+) - (Cl^- + HCO_3^-A)$

6 Maintenance

NOTE

Carry out all maintenance actions in accordance with the safety issues as described in chapter ! Safety Issues.

6.1 Maintenance Schedule

In order to keep up the reliability of the Combiline over a long period of time, it is necessary to carry out regular maintenance checks.

Check/maintenance	daily	weekly	quarterly	half yearly	s. chapter
Check filling level of Liquid Bottles/Bags	•				
Empty Waste Bottle	•				3.6.2
Check Printer Paper (replacement)	•				3.6.3
Check supply of Printer Paper	•				
Check pCO_2 (pH) calibr. parameters entered	•				3.5.3.1
Check Temperature and Air pressure	•				3.5.2.6
Quality control measurement	•				3.3
Check moisture filter bottle	•				6.3
Protein Removal after 100 tests or:		•			3.5.2.8
Cleaning of the COMBILINE's Housing		•			! 2
Cleaning of Sample Port + Waste Bottle cap		•			! 2
Disinfect Sample Port + Waste Bottle cap		•			! 2
Check Sensor status/parameter		•			3.5.1.6
Replace Roller Pump Tubes			•		6.6
Replace Sample Port Set including tube			•		6.7
General check by Technical Service				•	
Replace Pinch-Valve Tubes				•	
Exchange of inner tubings (incl. in service set)				•	
Check and adjustment of air-pressure				•	
Check and adjustment of thermostate temp.				•	
Check and adjustment of operating voltages				•	

Table 3Maintenance schedule

Test functions especially for the Technical Service:

Test BGA 1 / 3 pCO_2-Sensor: see chapt. 3.5.2.1
Test BGA 2 / 4 pCO_2-Sensor: see chapt. 3.5.2.2
Test CAL 3 pH/ISE-Sensor: see chapt. 3.5.2.3
Test CAL 4 (+M) pH/ISE-Sensor: see chapt. 3.5.2.4
Test GAS/pO_2: see chapter 3.5.2.5
Test Light Barrier: see chapter 3.5.2.7
Test Liquid Transport: see chapter 3.5.2.9

Maintenance schedule for Sensors

The time intervals listed in the following tables are calculated to an average throughput of tests. In times of a larger test throughput, the maintenance measures should be done earlier.

Membrane change:	4 weeks	8-12 weeks	3-6 months	6-9 months	s. chapter
pO_2		x			6.2.5.1
pCO_2		x			6.2.5.1
K^+			x		6.2.6.1
Na^+ (without membrane)					6.2.1/2
Ca^{++}			x		6.2.6.1
Cl^-			x		6.2.6.1
Li^+			x		6.2.6.1
GLU 1000 tests or:	30 days				
LAC 400 tests or:	15 days				
Ref.				x	6.2.11
pH (poss. regeneration)					6.2.3.1
					6.2.12

Table 4 Table Change of Membranes

Renewal of filling solution and check of conducting system:					
	4 weeks	8 weeks			s. chapter
pO_2*		8 - 12			6.2.5.1
pCO_2*		8 - 12			6.2.5.1
K^+		x			6.2.6.1
Na^+		x			6.2.6.1
Ca^{++}		x			6.2.6.1
Cl^-		x			6.2.6.1
Li^+		x			6.2.6.1
GLU (Biosensor)	not necessary				
LAC (Biosensor)	not necessary				
Ref.		x			6.2.11
pH (closed system)					6.2.3.1

Table 5 Renewal of filling solution/check of conducting system

*** : only together with a new membrane shell!**

The **replacement of the conducting systems** for K^+, Na^+, Ca^{++}, Cl^-, and Li^+-Sensors should be done when required; i. e., if the brown Ag/AgCl-coat is worn out or damaged. You can see it, if the colour of the conducting system has changed from brown to silver-grey (partly or whole).

To avoid a colour change, the conducting systems of the ISE-Sensors always should be filled with enough filling solution.

6.2 Maintenance of Sensors

Generals

Previous experience has shown that it is advisable to service the pO_2- and pCO_2-Sensors at intervals of approx. **8-12 weeks**.

The **maintenance interval** depends much on the number of the test throughput.

Maintenance of the pH, electrolyte- and Reference Sensors is limited mainly to checking the level of their filling solutions and refilling the solutions if necessary.

The best way to check the condition of the Sensors and their membranes is regular observance of the **slope parameter** in the menu "**SENSOR-PARAMETER**" of the OPERATION menu.

Another way of **checking the Sensors' function** and measuring accuracy is the use of **Quality Control Solutions**.

Basically there are two ways of carrying out maintenance of the Sensors:

1. Eschweiler customer service offers regenerated pO_2- and pCO_2-Sensors for exchange.

2. The user can use ready-made Membrane Casings and carry out cleaning of the pO_2- and pCO_2-Sensors himself. This method of Sensor maintenance is the more economical alternative.

When is it time to service or replace a Sensor?

Servicing/replacement of a Sensor becomes necessary when, after several weeks of operation, changes in the **sensitivity** of the Sensor or in the **stability** of measured results are noticed. Signs of this may be:

- Indication of a **slope error**.
- Slow **sinking of the slope** toward the lower limit of the permissible slope range.

- Slow **rising of the slope** of the pO_2-Sensor towards the upper limit of the permissible slope range.

- Indication of a **range-error**.
- Long measuring and calibration times.
- Nonreproducible measured results.
- **Results of the Quality Control** measurements outside the permissible tolerances.

NOTE

Before servicing for the above mentioned reasons, it is advisable to have a look at the measures discussed in chapter 4 Error messages!

Regeneration of Sensors

A regeneration of Sensors is only possible for pO_2-, pCO_2- and pH-Sensors. See chapter 6.2.3.1 and 6.2.5.1.

All the other ISE-Sensors can be refreshed by changing the membrane shell and the conducting system both with the corresponding filling solution (see chapter 6.2.6.1).

Sensor filling levels

Membrane shells for Na^+-, K^+-, Ca^{++}-, Cl^--, Li^+-Sensors must be filled until 2-3 mm below the upper edge.

The Ref-Sensor must be filled completely.
The pO_2- and pCO_2-Sensors must be filled until the red mark.

6.2.1 Removal of Sensors

The Sensors are located behind the white front cover below display. There in the solid state thermostat they form the measuring unit, lined up in a row. This set-up permits fast, convenient removal of the Sensors.

CAUTION

Open the REAGENT TEST menu before removal of a Sensor out of the array. This avoids any liquid penetration into the thermostate during maintenance measures.

To remove the Sensors:

- Run REAGENT TEST in the SERVICE-TEST menu and **keep the dialogue still displayed during this procedure!**
- Press 1-key for Suction, see chapter 3.5.2.9
- Open the front cover.
- Release the Sensor Catch by pulling on the right side.
- Remove the connected Cable from the Sensor.
- Remove the Sensor forwards (1) from the Sensor Array and lift it up (2) (see figure 17).

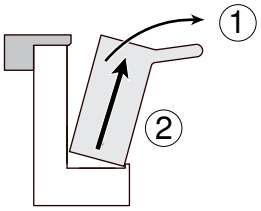


Figure 17 Sensor removal steps

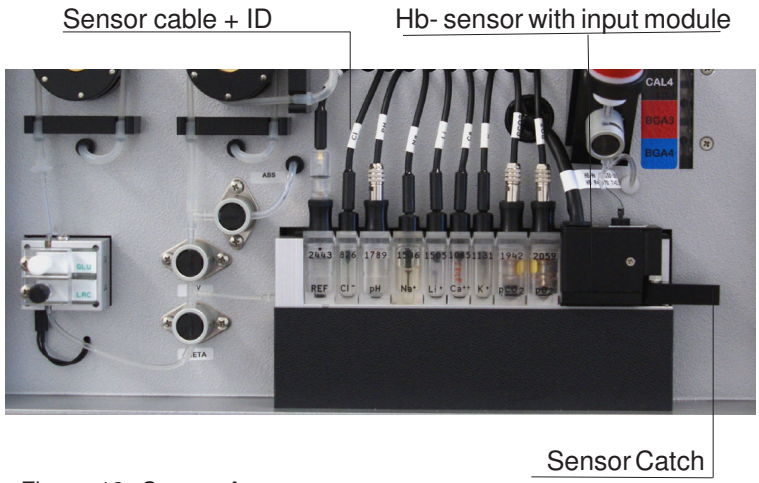


Figure 18 Sensor Array

6.2.2 Installation of Sensors

Proceed as follows:
- Run REAGENT TEST (s.chapter 6.2.1) menu during installation:
- Set the Sensor into the Sensor Array with the grip to the front (1). Pay attention to the Sensor position and don't damage the O-Ring!

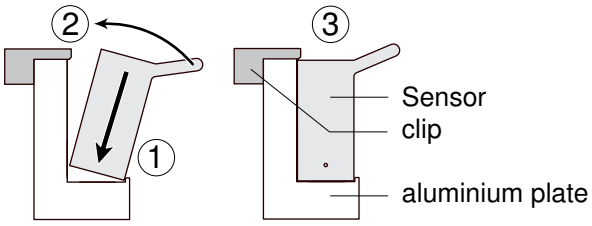


Figure 19 Sensor installation steps

The Sensor must perceptibly click into place at the rear! (2-3)
- Install further Sensors into their positions as described.

NOTE

During installation, make absolutely sure that all Sensors are clicked into the Sensor Array and their specimen channels form one continuous capillary!

- Close Sensor Catch by pushing it in closed position.
- Connect the appropriate Cables with the Sensors and pay attention to the identifications.

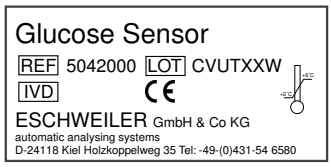
- Check the liquid flow using Wash function (2-key) or BGA 3 (3-key).

If the liquids transport function is ok, the liquids will be transported into the Waste Bottle. If not, a transportation malfunction is evident.
Check Sensor installation and go as described.

- Close the Cover.
- Press **QUIT**-key to return to the STAND BY menu.
- Wait until the temperature is stabilized to 37.0 °C ± 0.2, see Service - Test menu, select Air/Temp 6-key.
- Run a CALIBRATION cycle (OPERATION menu, **2**-key).

The STAND BY dialogue will appear after calibration.

Biosensors Glucose/Lactate



- Run REAGENT TEST in the SERVICE-TEST menu and **keep the dialogue still displayed during this procedure!**

- Take the corresponding Biosensor out of its package.
- Immediately put the Biosensor flushing into its right position. The upper position is for the Glucose sensor, the lower position for the Lactate sensor, see fig. 22.
  Make sure that:
  - the contact surface is placed inwards
  - the liquid contact place is on the left side

NOTE

Attention: while inserting of the Biosensor don't misplace the internal O-ring!

- Fasten the plastic screw carefully to fix the sensor in its position.
- For conditioning of the Biosensors touch **Meta** to fill the capillary with rinsing solution WASH 2 + M.

- Touch **Exit** to leave the dialogue and close the blue cover.

The Biosensors take about 120 min for conditioning and activation. After that a calibration cycle will be carried out automatically. The sensors then are ready for testing (marked green).

NOTE

Attention: Biosensors after its activation may not be kept dried over a longer time (1 hour)**. They would be damaged.**

Replacement of O-Rings

To replace the O-Rings of the Biosensor module, proceed as follows:

- Pay attention to the figures in chapter 6.2.13 and figure 22.
- Run REAGENT TEST in the SERVICE-TEST menu and **keep the dialogue still displayed during this procedure!**

- Press 1-key for Suction, see chapter 3.5.2.9
- Loosen the plastic fixing screws (2) and remove Biosensors.
- Unscrew the module retaining screws (1) with dishes.
- Put all dismantled parts onto a lint-free tissue.
- Pull the exposed O-Rings out of their position with a suitable tool.
- Replace O-Rings (No.: 50 2 10 25) in their positions with a suitable soft tool (pos.3)

- Assemble Biosensor module.
- Install Biosensors as described before.

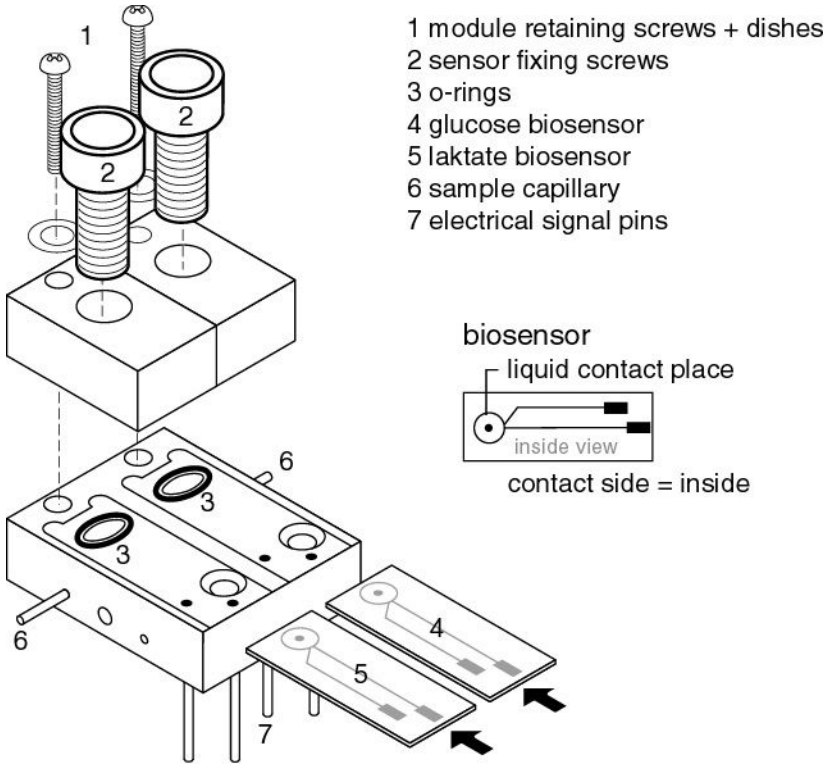


Figure 22 Biosensor measuring module

6.2.3 Principle of pH-measurement

The principle of the pH-measurement is based on the fact that an electrical potential difference occurs at a membrane made of pH-sensitive glass when this membrane separates two solutions with differing pH-values. The potential difference which thus occurs (voltage EpH) is proportional to the pH-difference of the two solutions.

UpH = 61.5mV* (pHx - pHo) at 37.0°C

*Nernst factor

The inside buffer solution pHo has a constant pH-value. Therefore the voltage EpH is proportional to the pH-value of the added specimen pHx which is to be determined.

The **conducting system** of the measuring Sensor makes the connection to the outside of the glass capillary membrane with the electrically conductive buffer solution. The conducting system of the Reference Sensor makes the connection to the inside of the glass capillary membrane with the electrolyte solution of the Reference Sensor, which also conducts electricity, and the specimen which is put in. With the connection thus made, the potential difference won by specimen pHx at the pH-glass-membrane is conducted to a measuring amplifier and displayed.

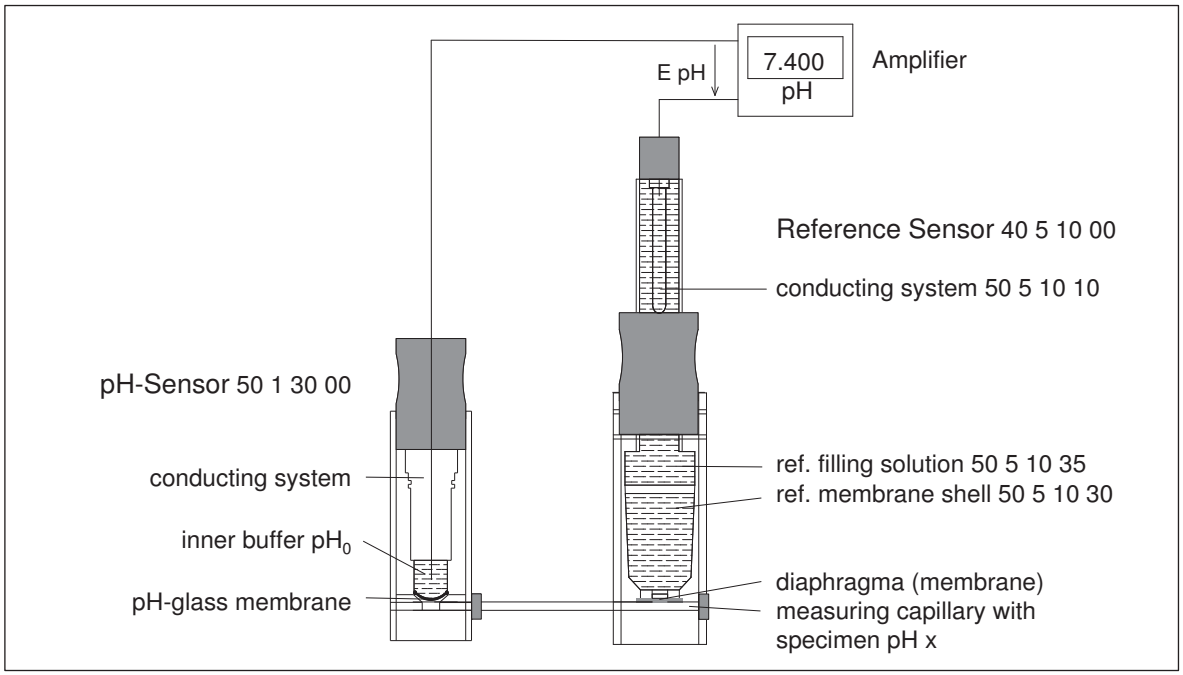


Figure 20 Construction of pH-Measuring chain

6.2.3.1 Regeneration of the pH-Sensor

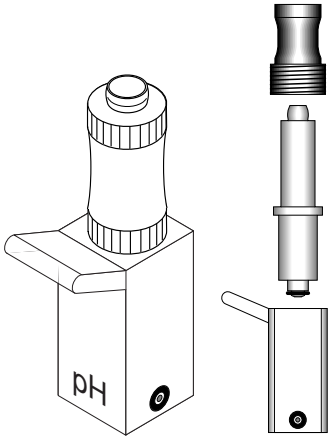
The pH-Sensor can be regenerated for several times. The polish of the glass-membrane should only be done when it is necessary!
The following maintenance accessories and expendable materials are required:

- Leather-covered cork 50 1 10 42
- Abrasive and cleaner (silicon carbide) 50 1 10 41
- Electrode cleaner 50 6 10 84 (alcoholic compounds)
- Adhesive tape
- Aqua Dist.
- Gloves

Regeneration procedure:

1. • Remove the pH-Sensor from the thermostat as described in chapter 6.2.1 Removal of Sensors.

2. • Unscrew the black cap of the Sensor (Illustr. a).



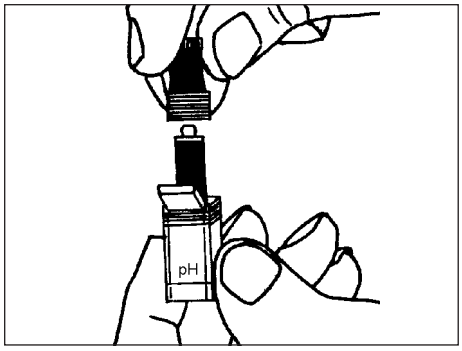


Illustration a

3. • Pull the pH-Sensor upwards out of the casing (Illustr. b).

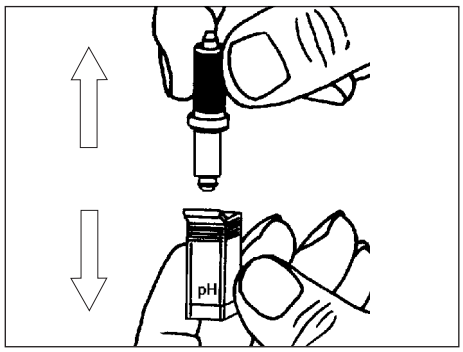


Illustration b

4. • Wipe off the glass membrane with a bit of **Electrode Cleaner** and a lint-free cellulose cloth (Illustr. c). **Don't remove the O-ring at the membrane!**

CAUTION

Do not remove the O-ring at the glass membrane while cleaning the membrane.

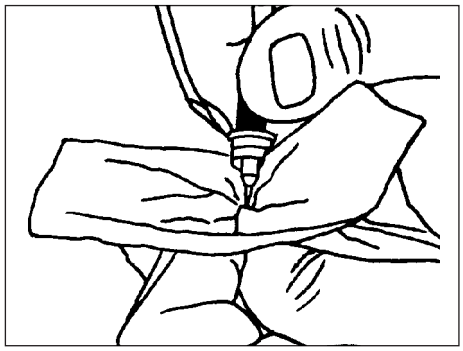


Illustration c

NOTE

Carry out step 6 to 8 only at extreme pollution or if the slope values are still down below 95%.

6. • Put some **Cleaning Paste** (Silicon Carbide order no.: 50 1 10 41) on the leather-covered cork and mix with a few drops of **distilled water** (Illustr. d).

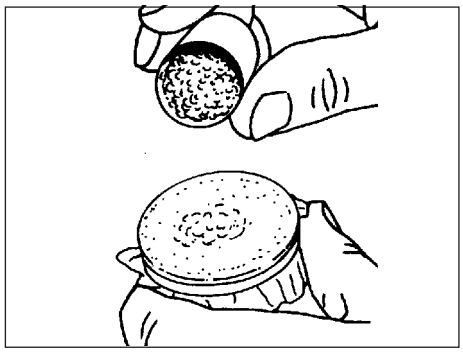


Illustration d

7. • Set the glass tip of the inside part vertically onto the prepared leather cork and **clean and polish with light pressure and for about 20 circular movements** on the leather (Illustr. e).

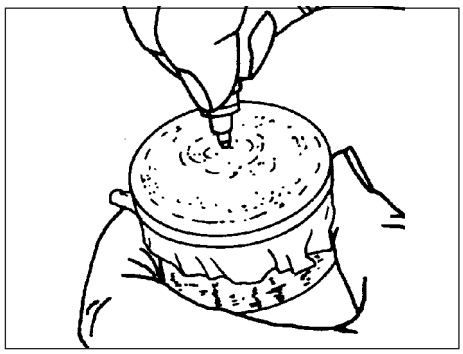


Illustration e

8. • Wipe off the shaft, and the glass membrane with a bit of **Electrode Cleaner** (order no.: 50 6 10 84) and a lint-free cellulose cloth (Illustr. c).

9. • Clean the inside part of the casing with a bit of **Electrode Cleaner** and a lint-free cellulose cloth. **Attention**: Don't drop electrode cleaner directly into the casing, the casing could be torn partly caused by evaporation-coldness.

10. • Put the inside part into the casing from the top and screw the cap onto the Sensor and tighten it slightly (Illustr. f).

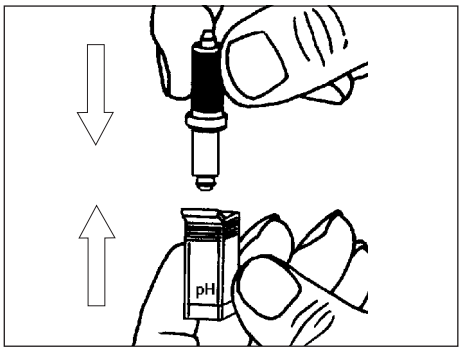


Illustration f

11. Return the cleaned Sensor into the Sensor Array as described in chapter 6.2.2 Installation of Sensors.

12. • Carry out a calibration cycle. (Run START CALIBRATION or CALIBRATION ISE only).
As the Sensors in the Combiline operate at a working temperature of 37.0 °C, a warming up period of about 30 minutes is recommended after regeneration (see function Air/Temp).

6.2.4 Principle of pCO_2-measurement

(according to Severinghaus)
Determination of the pCO_2 is based on the principle of an indirect pH-measurement. Here the pH-value is measured of a bicarbonate solution (pHx) which is separated from the specimen to be determined by a CO_2-permeable Teflon membrane. Through the membrane, CO_2 diffuses out of the specimen into the bicarbonate solution until a balance is reached between the two solutions. The resulting pH-change in the bicarbonate solution is directly proportional to the CO_2 diffused through the membrane.

$$pH = 6{,}1 + \log \frac{HCO_3^-}{S \times PCO_2}$$

Henderson Hasselbach-equation

$HCO3^-$	bicarbonate concentration in [mmol/l]
pCO_2	carbon dioxide partial pressure in [mmHg]
S	0.03 mmol/l x mmHg

The pH-change is measured as voltage difference by pH-glass-membrane which separates the bicarbonate solution and a reference solution with set pH-value. The reference system makes the electrical connection to the outside of the glass membrane with the conductive Bicarbonate Solution. The conducting wire in the inside of the electrode forms the electrical connection to the inside of the glass membrane with the conductive Reference Solution. The thus created voltage difference is transmitted to a measuring amplifier and displayed.

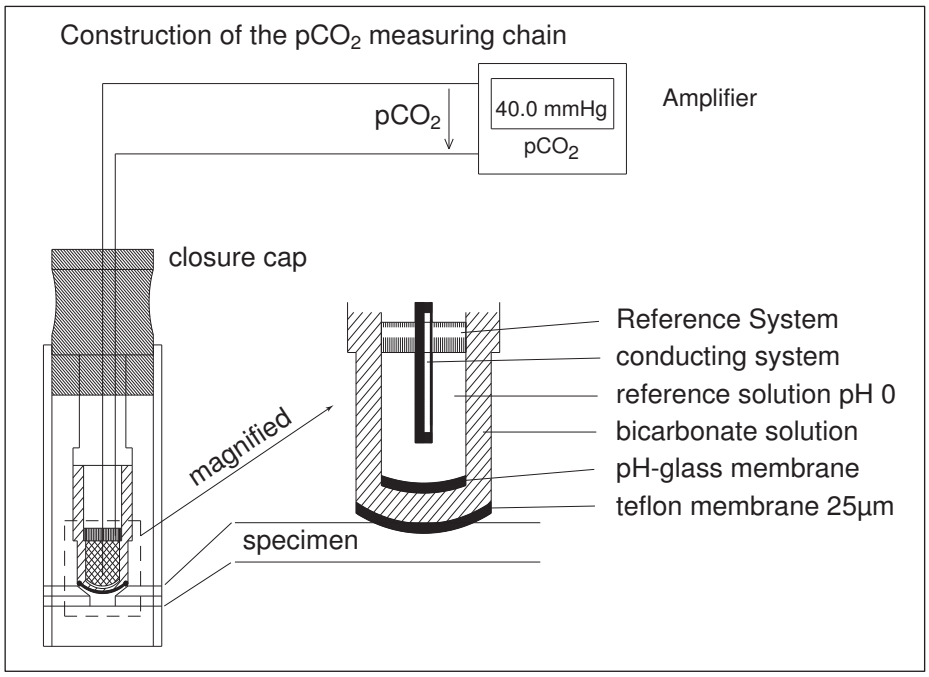
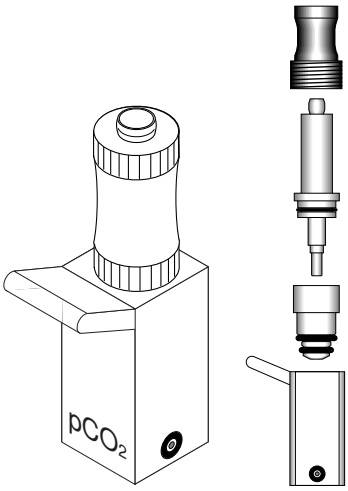


Figure 21 Construction of the pCO_2 measuring chain

6.2.4.1 Regeneration of the pCO_2-Sensor

NOTE

Polishing serves to regenerate the glass surface of the pCO_2 sensor unit in cases of low slope values.
Exchange of the Membrane shell is essential after polishing.
Do not install used membrane shells again!



The following maintenance accessories and expendable materials are required:

- Leather-covered cork 50 1 10 42
- Abrasive and cleaner 50 1 10 41
- Demineralised water (silicon carbide)
- Electrode cleaner 50 6 10 84 (alcoholic compounds)
- Cleaning tissue
- Adhesive tape
- Gloves

- pCO_2-filling solution 50 1 20 35
- pCO_2-membrane shell 50 1 20 30

Regeneration procedure (wear gloves for your own safety):

1. • Remove the Sensors from the Sensor Array as described in chapter 6.2.1 Removal of Sensors.

2. • Unscrew the black cap of the Sensor (Illustr. a).

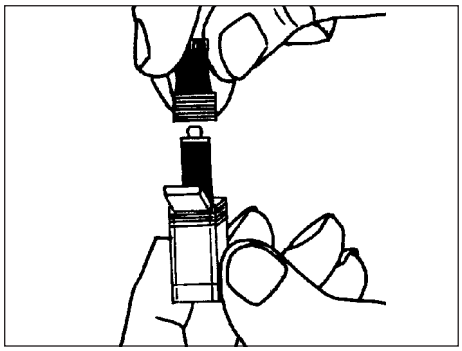


Illustration a

3. • Pull the pCO_2-Sensor upwards out of the casing (Illustr. b).

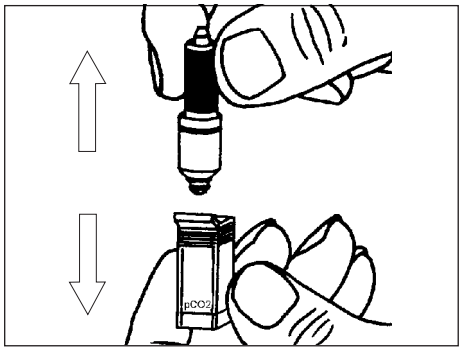


Illustration b

4. • Pull the used casing off the inside part while turning slightly (Illustr. c) (**Attention**: filling solution can be spilled out!).

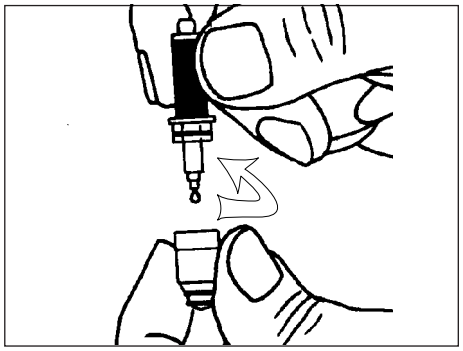


Illustration c

5. • Wipe off the shaft, the glass tip and the silver ring with a bit of Electrode Cleaner and a lint-free cellulose cloth (Illustr. d).

CAUTION

Attention: Do not wipe off the brown coloured silver/silver-chloride layer at pCO_2-Sensor!

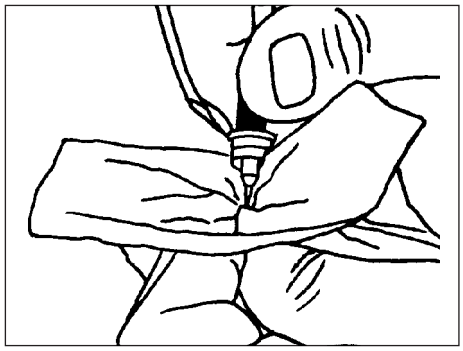


Illustration d

6. • Put some **Silicon Carbide** on the leather-covered cork and mix with a few drops of **distilled water** (Illustr. e).

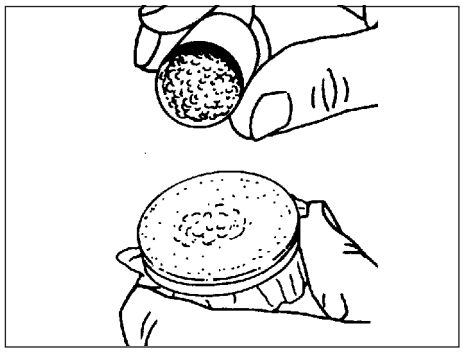


Illustration e

7. • Set the glass tip of the inside part vertically onto the prepared leather cork and **clean and polish with light pressure and about 20 circular movements** on the leather (Illustr. f).

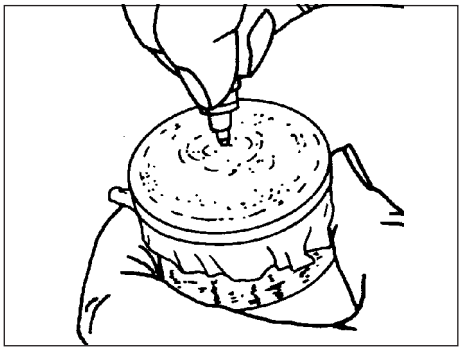


Illustration f

8. • Wipe off the shaft, the glass tip and the silver ring with a bit of electrode cleaner and a lint-free cleaning tissue (Illustr. d).

9. • Put 1-2 drops of Electrode Cleaner into a new membrane-covered casing and immediately spin it out again. (The Electrode Cleaner helps to prevent the formation of air bubbles when the filling solution is filled in).

10. • Fill the thus prepared casing to the red **filling mark** with pO_2-filling solution or with pCO_2-filling solution (approx. 7 drops). Fill the casing evenly and free of bubbles. **Please note, not to overfill the filling mark!** (Illustr. g).

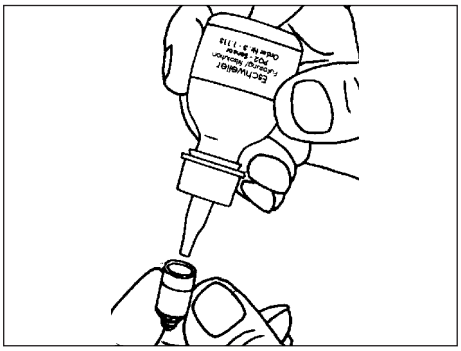


Illustration g

11. • Push the filled casing onto the Sensor with slight twisting movements. (Illustr. h). **Don't close the ventilation hole with your fingers**!

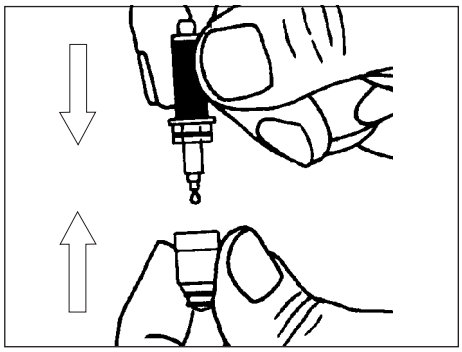


Illustration h

12. • Wipe off the outside of the Sensor and casing with a bit of Electrode Cleaner and a lint-free cleaning tissue. Then close the ventilation hole with a piece of yellow tape which is delivered together with the pre-membraned casings.

13. • Then clean the inside of the Sensor casing as well with a bit of Electrode Cleaner and a lint-free cellulose cloth.
Attention: Don't drop electrode cleaner directly into the casing, the casing could be torn partly caused by evaporation-coldness.

14. • Put the inside part into the casing from the top and twist slightly to the right or left until it clicks into the torsion protector (Illustr. i).

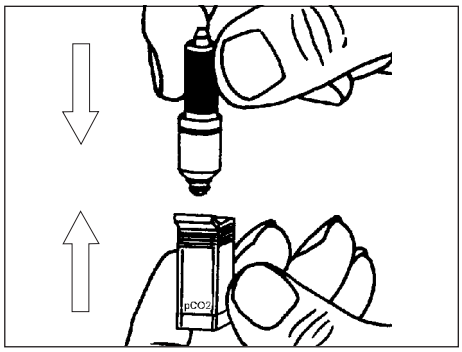


Illustration i

15. • Screw the cap onto the Sensor and tighten it slightly (Illustr. a).

16. Install the regenerated Sensor into the thermostat. (See chapter 6.2.2 Installation of Sensors).

17 Run a calibration cycle. (START CALIBRATION or CALIBRATION BGA). As the Sensors in the Combiline operate at a working temperature of 37.0 °C, a warming up period of about 30 minutes is recommended after regeneration.

6.2.5 Principle of pO_2-measurement

(according to Clark)
In determining the pO_2 the principle of polarography is employed. A typical current and voltage characteristic is used.
The oxygen molecules dissolved in a specimen (gas or solution) diffuse through the teflon membrane and are electrochemically reduced at the platinum cathode, which lies at a constant polarization voltage of -800 mV.

Through the electrons delivered by cathode and taken up by anode (reference system), a current flow occurs in the electrolyte. The current (current due to the concentration gradient) is taken up in the Combiline with a special measuring amplifier and displayed.
The height of the current due to the concentration gradient is proportional to the quantity of the oxygen molecules diffusing through the teflon membrane.

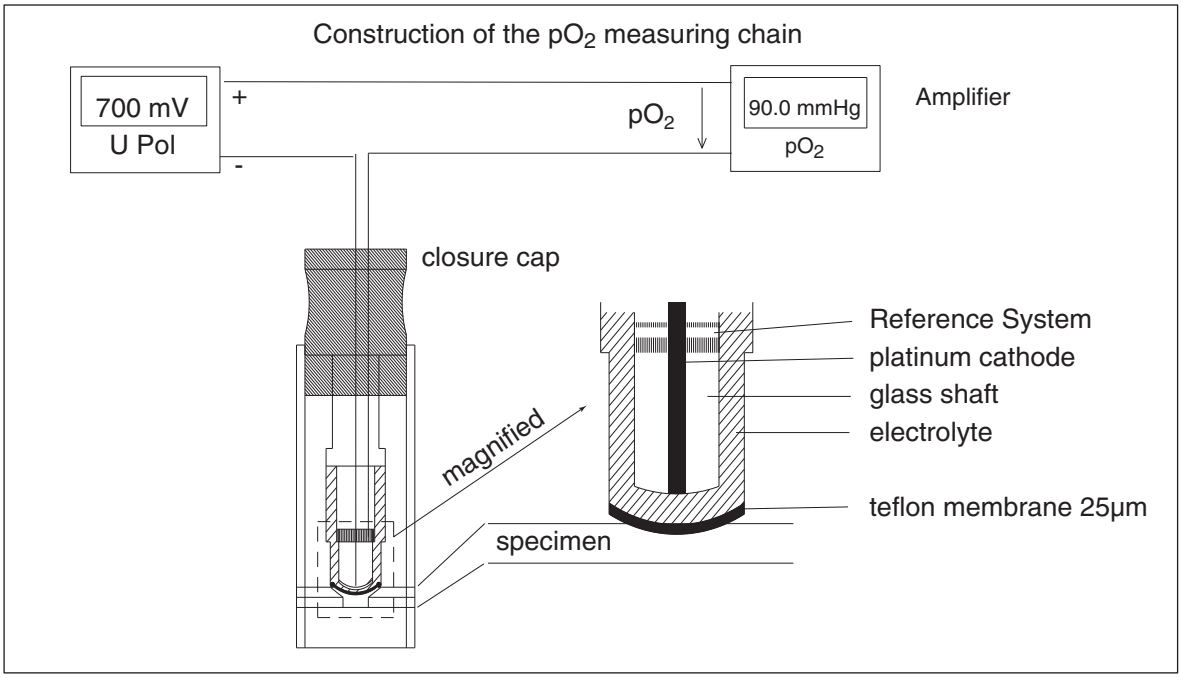
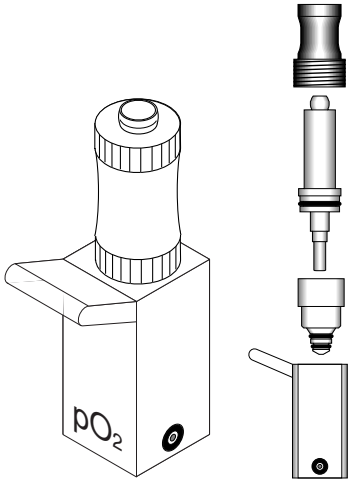


Figure 22 Construction of the pO_2-measuring chain

6.2.5.1 Regeneration of the pO_2-Sensor

NOTE

Deposits on the glass-surface of the pO_2 sensor unit can cause high slope values and pO_2 slope error indications.
Polishing serves to remove deposits from the glass surface of the pO_2 sensor unit.
Exchange of the Membrane shell is essential after polishing.
Do not install used membrane shells again!



The following maintenance accessories and expendable materials are required:

- pO_2-polishing-kit 50 1 10 50
- Demineralised water
- Electrode cleaner 50 6 10 84 (alcoholic compounds)
- Cleaning tissue
- Adhesive tape
- Gloves

- pO_2-filling solution 50 1 10 35
- pO_2-membrane shell 50 1 10 30

Regeneration procedure (wear gloves for your own safety):

1. • Remove the Sensors from the Sensor Array as described in chapter 6.2.1 Removal of Sensors.

2. • Unscrew the black cap of the Sensor (Illustr. a).

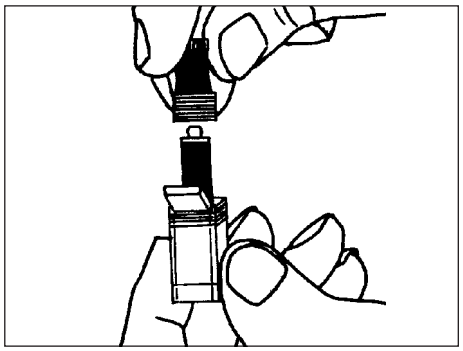


Illustration a

3. • Pull the pO_2- or pCO_2-Sensor upwards out of the casing (Illustr. b).

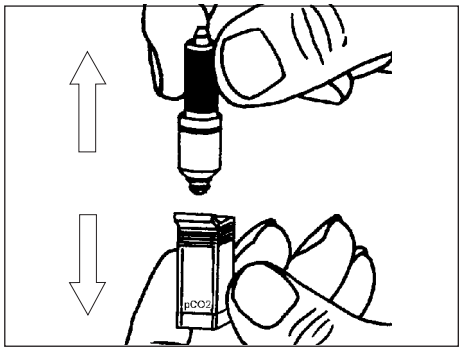


Illustration b

4. • Pull the used casing off the inside part while turning slightly (Illustr. c) (**Attention**: filling solution can be spilled out!).

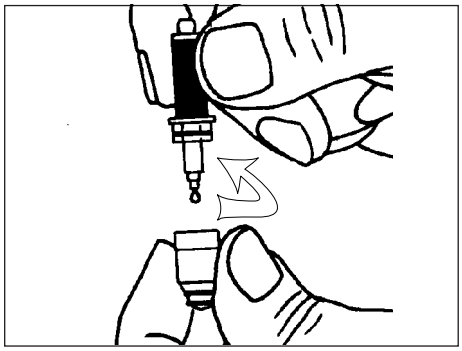


Illustration c

5. • Wipe off the shaft, the glass tip and the silver ring with a bit of Electrode Cleaner and a lint-free cleaning tissue (Illustr. d).

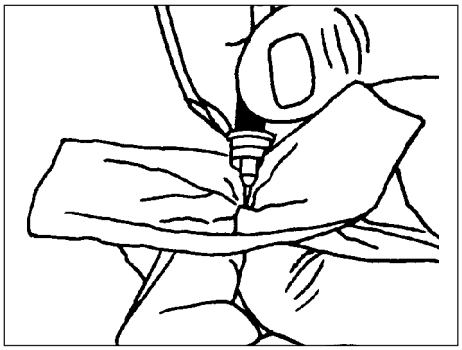


Illustration d

6. • Place some drops of demineralised water on the surface of the pO_2-polishing-kit (Illustr. e).

Illustration e

7. • Polish the glass-tip of the pO_2 sensor unit with circling movements on the polishing surface (illustr.f).
Continue polishing procedure for approx. 10 seconds.

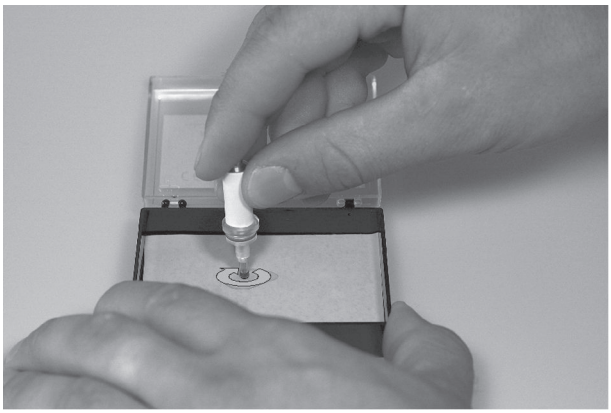


Illustration f

8. • Wipe off the shaft, the glass tip and the silver ring with a bit of electrode cleaner and a lint-free cleaning tissue (Illustr. d).

9. • Put 1-2 drops of Electrode Cleaner into a new membrane-covered casing and immediately spin it out again. (The Electrode Cleaner helps to prevent the formation of air bubbles when the filling solution is filled in).

10. • Fill the thus prepared casing to the red **filling mark** with pO_2-filling solution (approx. 7 drops). Fill the casing evenly and free of bubbles. **Please note, not to overfill the filling mark!** (Illustr. g).

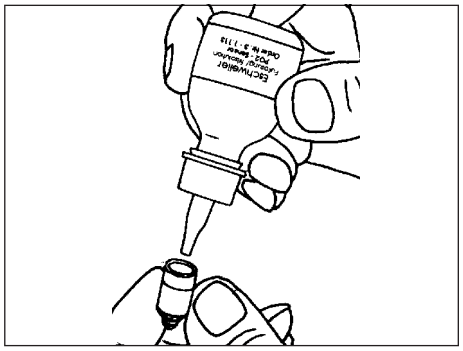


Illustration g

11. • Push the filled casing onto the Sensor with slight twisting movements. (Illustr. h). **Don't close the ventilation hole with your fingers**!

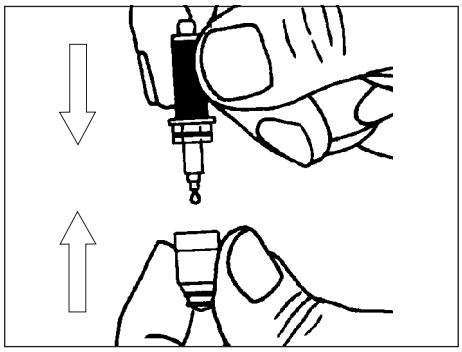


Illustration h

12. • Wipe off the outside of the Sensor and casing with a bit of Electrode Cleaner and a lint-free cleaning tissue. Then close the ventilation hole with a piece of yellow tape which is delivered together with the pre-membraned casings.

13. • Then clean the inside of the Sensor casing as well with a bit of Electrode Cleaner and a lint-free cellulose cloth.
Attention: Don't drop electrode cleaner directly into the casing, the casing could be torn partly caused by evaporation-coldness.

14. • Put the inside part into the casing from the top and twist slightly to the right or left until it clicks into the torsion protector (Illustr. i).

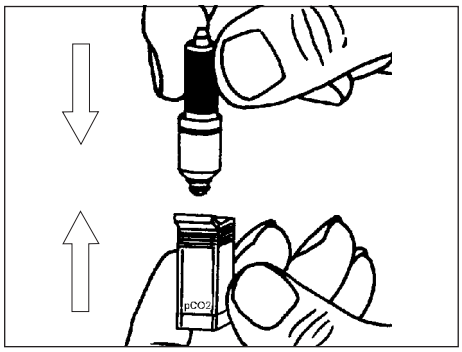


Illustration i

15. • Screw the cap onto the Sensor and tighten it slightly (Illustr. a).

16. Install the regenerated Sensor into the thermostat. (See chapter 6.2.2 Installation of Sensors).

17 Run a calibration cycle. (program CALIBRATION or CALIBRATION BGA). As the Sensors in the COMBILINE operate at a working temperature of 37.0 °C, a warming up period of about 30 minutes is recommended after regeneration.

6.2.6 Principle of K^+ -measurement

The principle of the K^+-measurement is based on the fact that at a PVC-membrane which is permeable for K^+-ions an electrical potential difference occurs when this membrane separates two solutions with different K^+-values. The resulting potential difference (voltage EK^+) is proportional to the difference of the K^+-ion concentrations for the two solutions.

$UK^+ = -61.5mV^* (K^+x - K^+o)$ at 37,0 °C

*Nernst factor

The inner buffer solution K^+ has a constant K^+-concentration. Therefore the voltage EK^+ is proportional to the potassium ion concentration of the added specimen K^+x, which is to be determined.

The conductive system of the measuring Sensor makes the connection to the outside of the K^+-PVC membrane with the electrically conductive filling solution. The conductive system of the Reference Sensor makes the connection to the inside of the PVC membrane with the electrically conductive electrolyte solution of the Reference Sensor and the added specimen. With this connection the potential difference won through a specimen K^+x at the PVC membrane is conducted to a measuring amplifier and displayed.

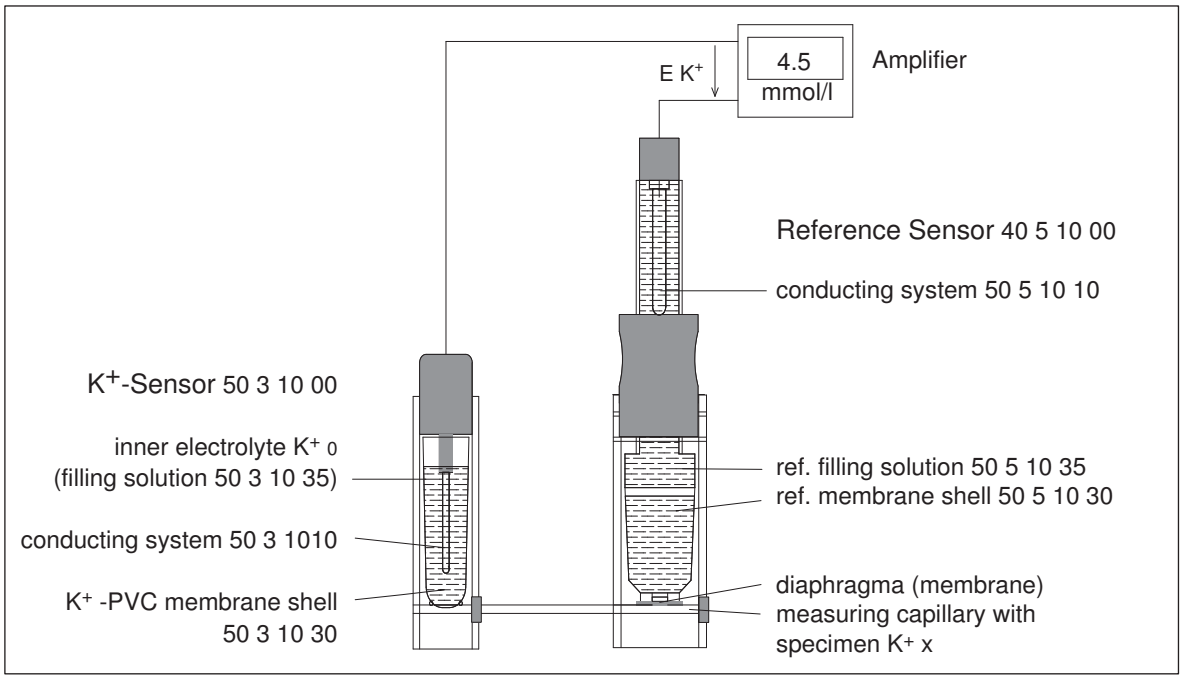


Figure 23 Set-up of K^+-measuring chain

6.2.6.1 Exchange of the ISE-Sensor Membrane Shell

To exchange a membrane shell or conducting system of one of the ISE-Sensors (K^+, Ca^{++}, Cl^-, Li^+), proceed as follows:

NOTE

To assure a perfect function of the ISE-Sensors, check the filling level weekly. If necessary fill it up! Check also the conducting system regarding its coat colour. It should be brown.

NOTE

Check the Na^+-Sensor (without membrane shell) regarding its filling level. If necessary fill it up! Check also its conducting system regarding its coat colour. It should be brown.

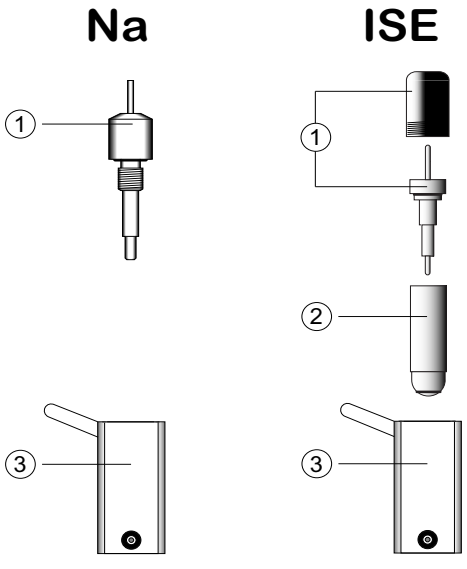
1 • **Remove** the ISE-Sensor out of the Array as described in chapter 6.2.1 Removal of Sensors.

2 • **Unscrew** the conducting system together with the membrane shell out of the casing.

3 • **Pull** the membrane shell out of the conducting system and dispose it.

CAUTION

The conducting system of the ISE-Sensors must not be cleaned because the brown-coloured coat will be damaged. If the colour has changed to white or silver, the conducting system must be replaced.



1 conducting system
2 membrane shell
3 sensor casing

Figure 24 ISE-Sensors (exploded view)

Filling level of the membrane shells

4 • **Fill up** the new membrane shell to 75% with the corresponding filling solution. Avoid air-bubbles inside the solution otherwise a Slope error message could occur. Use your fingers to tip on the shell to remove air-bubbles.

5 • **Lead** the conducting system (new) into the membrane shell so that it fits closely with it.

6 • **Clean** the Sensor casing inside with a lint-free cloth and with some drops of electrode cleaner. **Attention:** Don't drop electrode cleaner directly into the casing, the casing could be torn partly caused by evaporation-coldness.

7 • **Screw** the Sensor carefully back into the casing.
8 • **Install** Sensor into its position as described in chapter 6.2.2 Installation of Sensors.

9 • **Carry out** a calibration cycle after installation. Make sure that the analyser is already warmed up!

NOTE

After warming up entirely, air-bubbles could be present inside of the refilled membrane shell and could cause a Slope error message. If that happened, go back to step 4 to remove air-bubbles.

6.2.7 Principle of the Na^+-measurement

The principle of the Na^+-measurement is based on the fact that at a membrane made of Na^+-sensitive glass an electrical potential difference occurs when this membrane separates two solutions with different Na-values. The resulting potential difference (voltage ENa^+) is proportional to the difference of the Na^+-ion concentrations of the two solutions.

ENa^+ 0 -61.5mV* (Na^+x - Na^+o) at 37.0°C

*Nernst factor

The inner buffer solution Na^+0 has a constant Na^+-concentration. Therefore the voltage ENa^+ is proportional to the Na-value of the added specimen Na^+x, which is to be determined.

The conducting system of the measuring Sensor makes the connection to the outside of the glass capillary membrane with the electrically conductive buffer solution. The conducting system of the Reference Sensor makes the connection to the inside of the glass capillary membrane with conductive electrolyte solution of the Reference Sensor and the added specimen. With the connection thus made, the potential difference won through a specimen Na^+x at the Na-glass-membrane is conducted to a measuring amplifier and displayed.

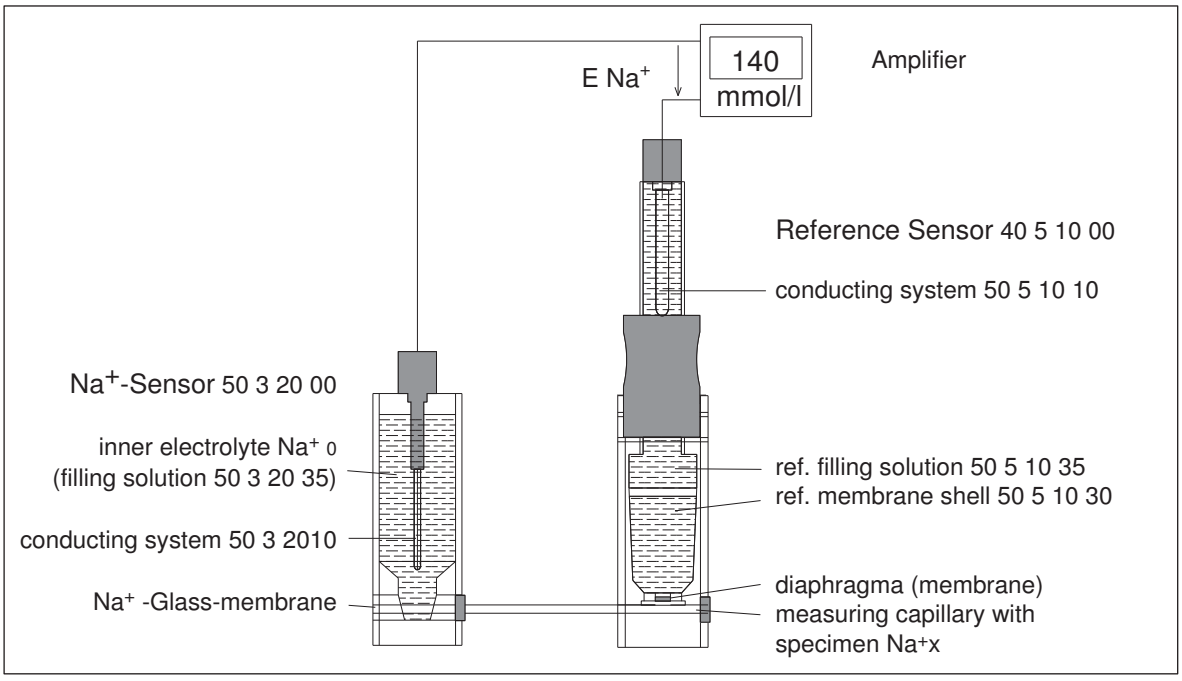


Figure 24 Set-up of the Na^+-measuring chain

6.2.8 Principle of Ca^{++}-measurement

The principle of the Ca^{++}-measurement is based on the fact that at a PVC-membrane which is permeable for Ca^{++}-ions an electrical potential difference occurs when this membrane separates two solutions with different Ca^{++}-values. The resulting potential difference (voltage EK^{++}) is proportional to the difference of the Ca^{++}-ion concentrations for the two solutions.

$UCa^{++} = -30.75mV^* (Ca^{++}_X - Ca^{++}_0)$ at 37.0 °C

*Nernst factor

The inner buffer solution Ca^{++} has a constant Ca^{++}-concentration. Therefore the voltage ECa^{++} is proportional to the calcium ion concentration of the added specimen $Ca^{++}x$, which is to be determined.

The conductive system of the measuring Sensor makes the connection to the outside of the Ca^{++}-PVC membrane with the electrically conductive filling solution. The conductive system of the Reference Sensor makes the connection to the inside of the PVC membrane by electrically conductive electrolyte solution of the Reference Sensor and the added specimen. With this connection the potential difference won through a specimen $Ca^{++}x$ at the PVC membrane is conducted to a measuring amplifier and displayed.

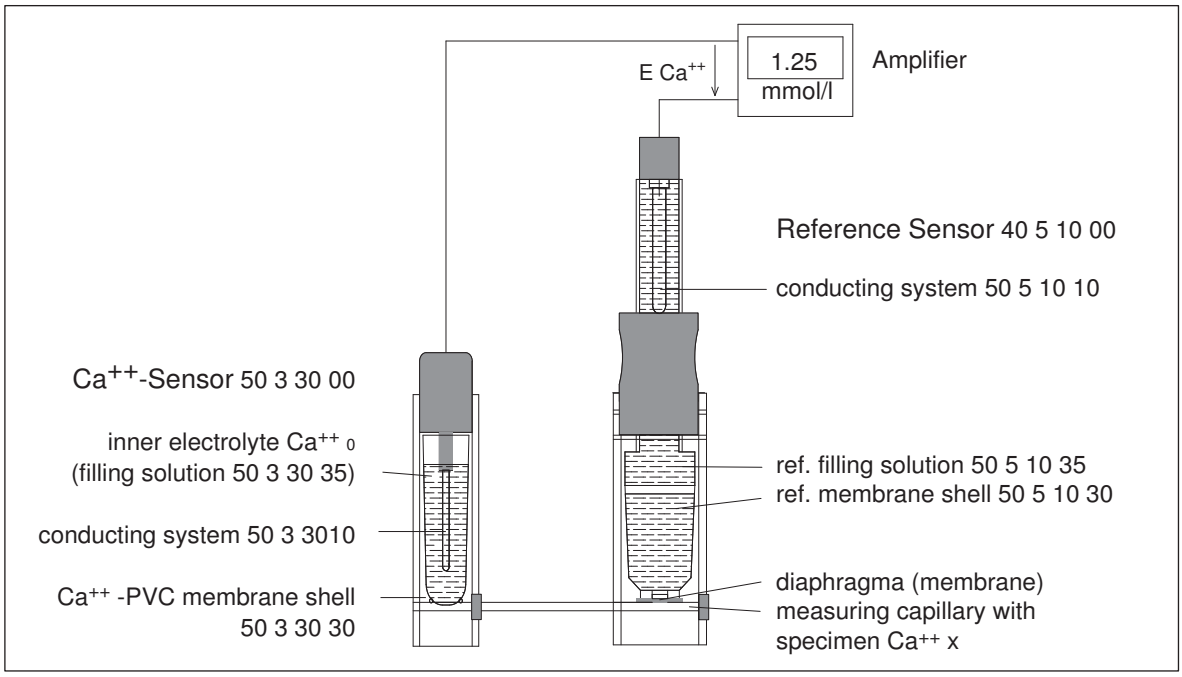


Figure 25 Set-up of the Ca_{++} -measurement chain

6.2.9 Principle of Cl^- -measurement

The principle of the Cl^--measurement is based on the fact that at a PVC-membrane which is permeable for Cl^--ions an electrical potential difference occurs when this membrane separates two solutions with different Cl^--values. The resulting potential difference (voltage ECl^-) is proportional to the difference of the Cl^--ion concentrations for the two solutions.

$UCl^- = -61.5mV^* (Cl^-x - Cl^-o)$ at 37.0 °C

*Nernst factor

The inner buffer solution Cl^- has a constant Cl^--concentration. Therefore the voltage ECl^- is proportional to the chloride ion concentration of the added specimen Cl^-x, which is to be determined.

The conductive system of the measuring Sensor makes the connection to the outside of the Cl^--PVC membrane with the electrically conductive filling solution. The conductive system of the Reference Sensor makes the connection to the inside of the PVC membrane with the electrically conductive electrolyte solution of the Reference Sensor and the added specimen. With this connection the potential difference won through a specimen Cl^-x at the PVC membrane is conducted to a measuring amplifier and displayed.

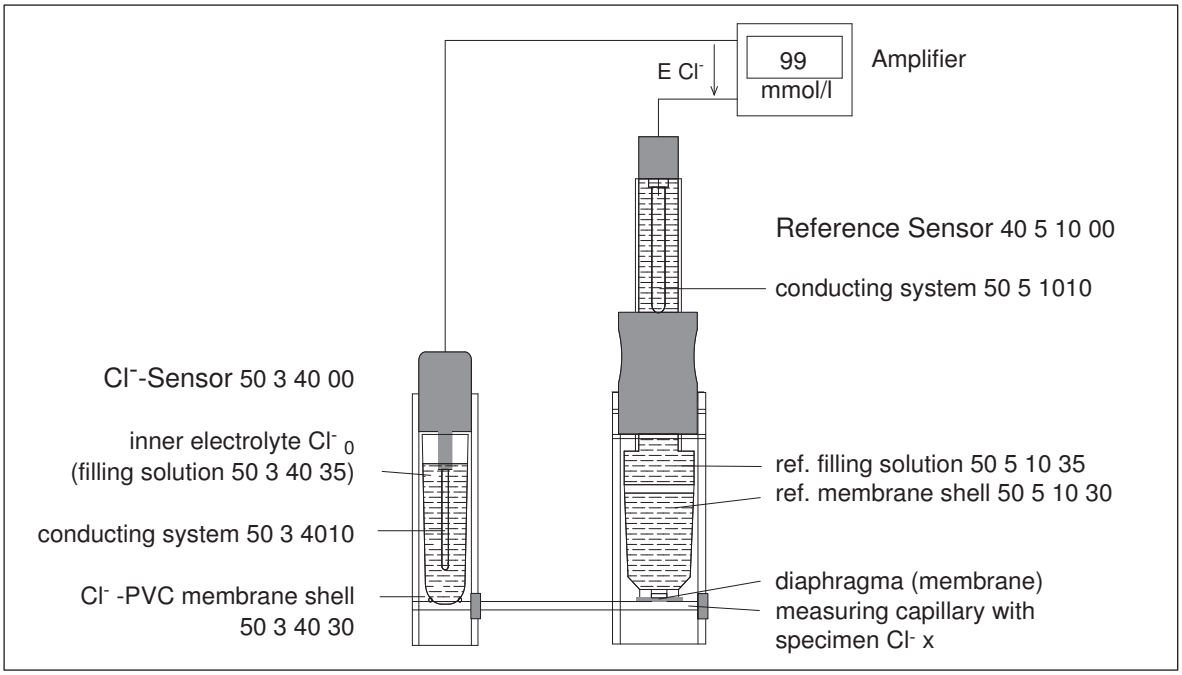


Figure 26 Set-up of the Cl^- -measuring chain

6.2.10 Principle of Li^+ - measurement

The principle of the Li^+-measurement is based on the fact that at a PVC-membrane which is permeable for Li^+-ions an electrical potential difference occurs when this membrane separates two solutions with different Li^+-values. The resulting potential difference (voltage ELi^+) is proportional to the difference of the Li^+-ion concentrations for the two solutions.

$ULi^+ = -61.5mV^* (Li^+x - Li^+o)$ at 37.0 °C

*Nernst factor

The inner buffer solution Li^+ has a constant Li^+-concentration. Therefore the voltage ELi^+ is proportional to the lithium ion concentration of the added specimen Li^+x, which is to be determined.
The conductive system of the measuring Sensor makes the connection to the outside of the Li^+-PVC membrane with the electrically conductive filling solution. The conductive system of the Reference Sensor makes the connection to the inside of the PVC membrane with the electrically conductive electrolyte solution of the Reference Sensor and the added specimen. By this connection the potential difference won through a specimen Li^+x at the PVC membrane is conducted to a measuring amplifier and displayed.

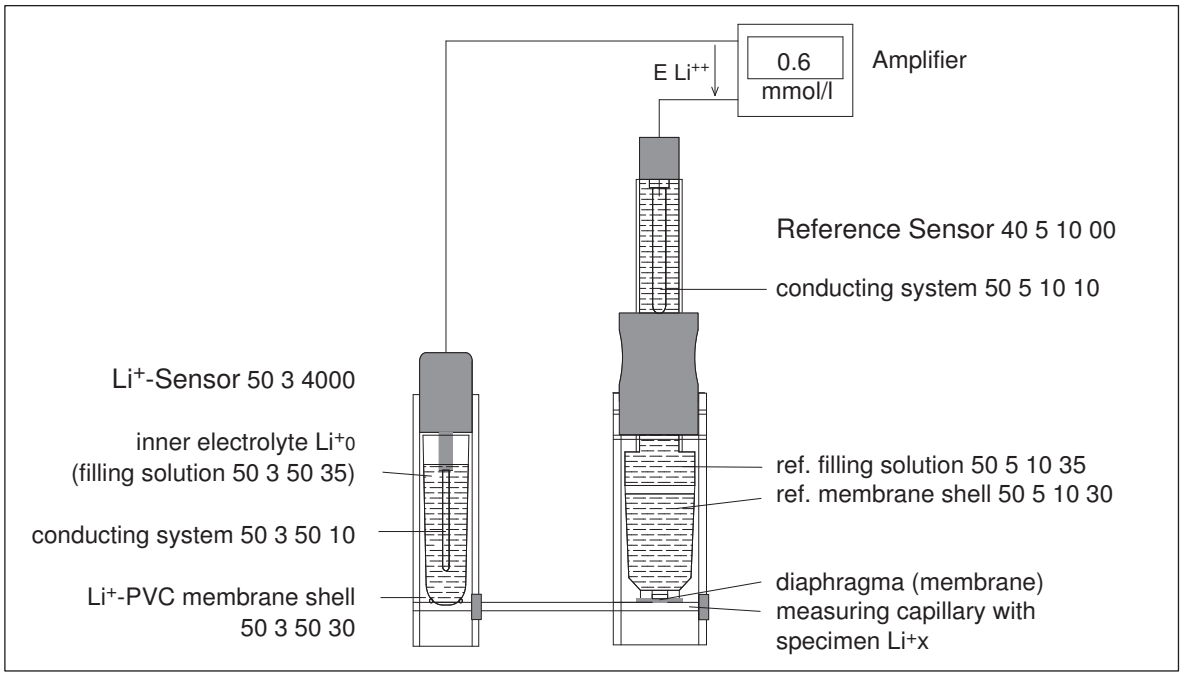


Figure 27 Set-up of the Li+-measuring chain

6.2.11 Reference Sensor

Filling solution

We recommend **replacing the filling solution of the Reference Sensor every three months**. *It has to be changed at the latest when the electrode voltages UK1 and UK2, in particular that of the pH-Sensor (see Sensor Parameter), exceed +3Volt or -3V*.

Conducting system

The reference conducting system basically requires no maintenance; however, it *must not stand **dry** over a longer period* of time (several hours).
The reference conducting system absolutely must always be covered with sufficient filling solution, even including inside the reference Sensor casing. Otherwise the function of the Reference Sensor will be impaired. This generally leads to **slope errors** of the pH- and ISE-Sensors or to distortion of the measured values.
The level of the filling solution should be checked every four weeks and filled up as needed.

Reference casing with membrane

The reference membrane casing has an average life span of approx. **six to nine months**, depending on the number of specimen measurements which are carried out. It *has to be replaced* at the latest *when the electrode voltages UK1 and UK2 of the ISE- and pH-Sensors (see Sensor Parameters) exceed +3Volt or -3V or when **slope errors** are indicated for these Sensors*.

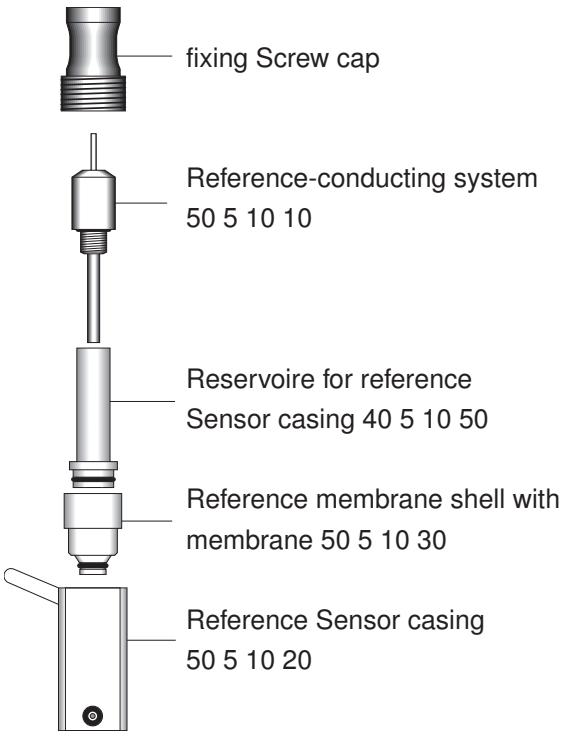


Figure 28 Reference Sensor complete

Reference Sensor complete 40 5 10 00

For Replacement of the Reference Membrane casing proceed in the following order:

1. • To replace the Reference Membrane casing, remove the Reference Sensor as described in chapter 6.2.1 Removal of Sensors.

2. • **Unscrew** the cap and pull it upward off.

3. • **Take** the now loose inner part completely out by lifting it up out of the Sensor casing.

4. • **Unscrew** the reference conducting system. It mast not dry out over a longer time!

5 • **Spin out** the filling solution (use a paper towel to catch the solution.

6 • **Pull** the used membrane casing off the attachment.
7 • Push a new Reference Membrane casing over the O-ring of the attachment.

8 • **Fill** the casing and membrane shell through the upper opening of the attachment almost completely with reference filling solution 50 5 10 35. If there are any air bubbles directly above the membrane, cause them to rise by tapping on the outside of the membrane casing. Air bubbles at this location cause "slope error" indications for the pH- and ISE-Sensors!

9 • **Screw** the conducting system into the upper opening of the attachment. **Attention**: Filling solution can be spilled out!

10 • **Clean** the Sensor casing inside with a lint-free cloth and with some drops of electrode cleaner. **Attention:** Don't drop electrode cleaner directly into the casing, the casing could be torn partly caused by evaporation-coldness.

11 • **Set** the complete internal core back into the casing by turning it slightly to get into its proper position. Reassemble the closing cap.

12 • **Install** the Reference Sensor in its position as described in chapter 6.2.2 Installation of Sensors.

13 • **Carry out** a calibration cycle after reinstallation. Make sure that the temperature is already warmed up (30 minutes)!

After warming up entirely, air-bubbles could be present inside of the refilled membrane shell and could cause a Slope error message for pH- and ISE-Sensors. If that happened, go back to step 4 to remove air-bubbles.

6.2.13 Metabolite Sensors

Storage
In refrigerator at 2 – 8 °C in closed original package.

Lifetime
GLU = 1000 samples or approx. 30 days
LAC = 400 samples or approx. 15 days (lactate typ L)

Rinsing solution
WASH+M (order no. 50 6 10 15)

Calibration solution
CAL4+M (order no. 40 6 10 56)
GLU = 5.0 mmol/l, LAC = 5.0 mmol/l; (Na^+ = 155!)

Measurement
Successive measurement of Hb, BGA+ISE and Metabolites.

Precision
GLU: 0.0 - 20.0 mmol/l = 5%, 20.0 - 30.0 mmol/l = 10%
LAC: 0.0 - 10.0 mmol/l = 5%, 10.0 - 20.0 mmol/l = 10 – 15%

Units
GLU: 1 mmol/l = 18.02 mg/dl
LAC: 1 mmol/l = 9.008 mg/dl

Slope ranges
GLU: 30 – 300%
LAC: 30 – 300%

Measurement
Successive measurement of Hb, BGA+ISE and Metabolites.

Sensors are not allowed to be kept dry for more of 1 hour after activation! Otherwise Sensors may get damaged irreversibly.

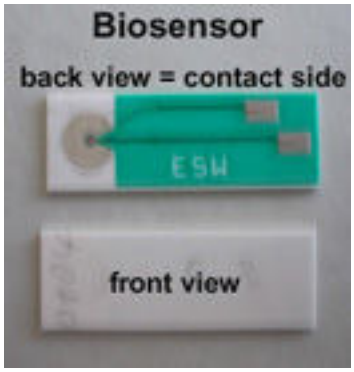


Figure 30: Biosensor, backside and front side view

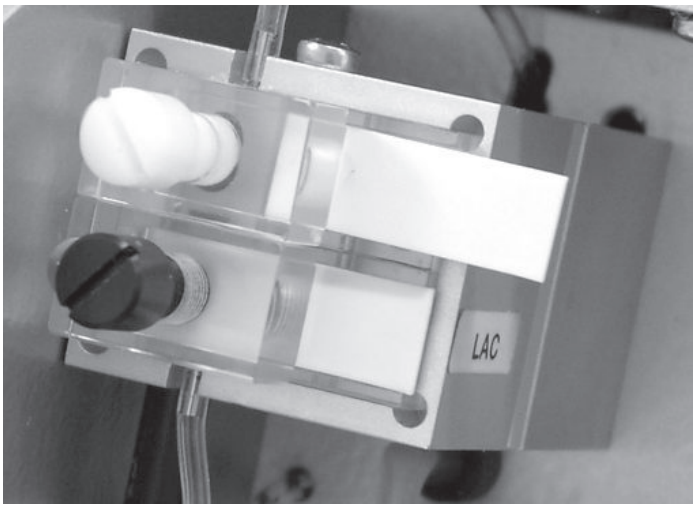


Figure 30a Biosensor module
White plastic screw is unlocked. Glucose sensor is out of working position.

Installation

After unpacking, immediately install the sensors into the Metabolite sensor-unit (upper slot = Glucose sensor, lower slot = Lactate sensor).
Before installation activate the REAGENT TEST program in menue SERVICE (key 9). Then press key 7 (Gas) to to empty the measuring cell.
To install the sensor strips, loosen the corresponding screw at the Metabolite sensor-unit and remove the old sensor strip by pulling it out to the right side.
Then carefully insert the new sensor strip.
Attention! Do not displace the O-ring (5.0x1.0) inside the Metabolite sensor-unit. Fasten the screw again.
Then stop the REAGENT TEST with the QUIT key. Metabolite sensors will automatically be filled with WASH2+M solution for conditioning then.
The Metabolite Sensors need approx. 120 minutes for conditioning and activation of the enzyme membranes.
After conditioning and calibration, the sensors are ready for use.

Measurement

Successive measurement of Hb, BGA+ISE and Metabolites.

1. Feeding of sample (by operator).
2. Hb-measurement.
3. BGA + ISE measurement.
4. Specimen transport to Metabolite sensors with following measurement of GLU and LAC.
5. Rinsing of the measuring cells with WASH2+M.

CAUTION

Sensors are not allowed to be kept dry after activation in the analyser! Sensors may get damaged irreversible otherwise.

6.3 Moisture Absorber

Purpose

The purpose of the Moisture Absorber is to protect the Vacuum Pump from the suck in of moisture. This Absorber collects the moisture and must be removed by opening of the screw at the bottom.
The moisture absorber is located behind the front-panel inside the combi*line* housing. Accessible for Service staff only!

Siphon off of the Moisture Absorber

Biohazard

In case that the Absorber is filled with moisture, it must be emptied by authorized service personnel as described as follows:

- Open the front panel
- **Wear gloves** for your own safety (**biological material!**)
- Hold absorbing cloth under the Absorber and open the plastic screw. The collected moisture drops out.

- After emptying, carefully turn the plastic screw in.
- Press the Absorber back in its feeder clip.

6.4 Fuse Replacement

Only a trained person should do this kind of work. If a fuse is burned you have to find out the reason!

If the fuse needs to be replaced or controlled proceed as follows:

- **Switch OFF** the Combiline!
- **Disconnect** the power cord between Combiline and mains!

- Carefully pull out the fuse compartment by a screwdriver as shown in figure 31.

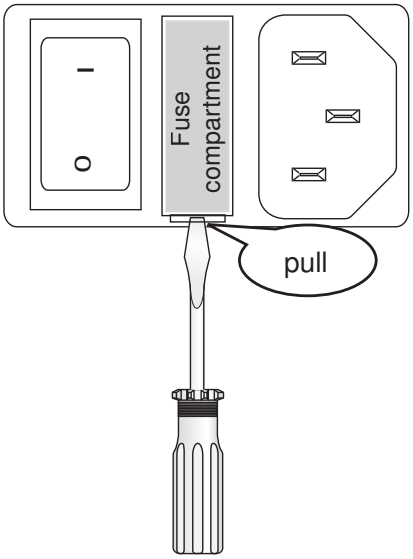


Figure 31 Fuse compartment

- Check the fuses. If the fuse is burned, replace it by a fuse of the same type (230V / 2.5 A time lag). Don't repair a fuse! The accessory kit supplies different type of fuses. The fuse-types 1A and 2A are for internal use by the Technical Service only!

- Insert the fuse compartment in its housing.
- Reconnect Combiline to power supply and check proper operation.

Contact authorised customer service in case that the exchange of fuse has been unsuccessful. **Note** that the operating voltage is set by the manufacturer and cannot be changed by the user!

6.5 Fan

The Combiline needs to be cooled by a built-in fan at the rear.
The Fan is located at the rearside. **Make sure that the air outlet is not covered!** Filter exchange is not required

6.6 Replacement of Roller Pump Tubes

Roller Pump Tubes are equipped with two Stoppers (strengthened parts) near both ends. For the transport of exact amounts of liquids the Tubes must be tentioned over the Roller Pumps. The **R**oller **P**ump 2 is for testing of Lactate and Glucose and is available in combi*line* meta versions only. The tubes should be replaced according to the maintenance schedule!

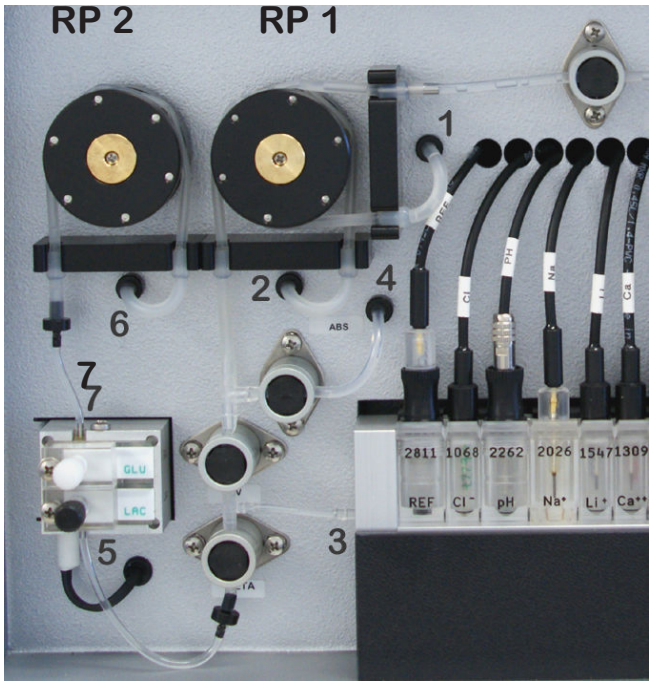


Figure 32 Roller Pumps

For the replacement or installation of the Tubes for the Roller Pump proceed as follows:

- Change to the REAGENT TEST dialogue (see chapter 3.5.2.9).
- Press the corresponding SUCTION-key for about 2 sec to empty the Tubes.
- Remove the Tubes to be replaced at the Roller Pumps and remove the parts from Liquid System Adapters 1, 2, 4, 5, 6 and 7.

Installation

Roller Pump tube for Reagents (RP1)

- Put the new Tube to the connectors 2, 3, 4 and 5 and connect it with the tube at position 3 as shown in figure 32.
- Pull the Tube through the lower Tension Block and position both Stoppers into the **Stopper-section at the back** (see figure 32).
- Carefully pull the Tube over the upper Roller Pump.

Roller Pump tube for WASH (RP1)

- Put the new Tube to the connector 1 and fit the other into the WASH valve and connect the end with the sample-port insert as shown in figure 32.

- Pull the Tube through the right Tension Block and position both Stoppers into the **Stopper-section at the front** (see figure 32).

- Carefully pull the Tube over the lower Roller Pump.
- Press the 7-key GAS for some seconds to align the tubes.
- Press QUIT-key to return to the STAND BY dialogue.

Roller Pump tube for Metabolites (Roller Pump RP2)

- Put the new Tube to the connectors 6 and 7.

- Pull the Tube through the Tension Block and position both Stoppers into the **Stopper-section** (see figure 32).

- Carefully pull the Tube over the upper Roller Pump.

6.7 Replacement of Sample-Port-Adapter

The Sample-Port-Adapter to fix up Syringes or Capillaries must be replaced according to the maintenance schedule. A replacement set is available by manufacturer: Order no.: 1-8.106.

Proceed as described as follows:

- Open the dialogue REAGENT TEST in SERVICE - TEST menu.
- Remove the white front-cover.

- Pull the WASH tube out of the red sample port insert
- Screw the red sample port insert counterclockwise out of its white holder.
- Take a new sample port insert and turn it clockwise into the holder. The hole for connection of the WASH tube must point to left top.
- Put the WASH tube into the corresponding hole of the sample port insert
- Press the 2-key WASH for some seconds to let WASH solution flow through the system.
- Press QUIT-key to return to the STAND BY dialogue.

6.8 Disposal of the Combiline

In case of disposing the combi*line* ask your representative if he takes the analyser back.
In other cases following features should be observed:

- Make sure that the Combiline has been decontaminated before disposal.

Mechanical parts are mostly made of aluminium and precious metal.

- Electronic parts must be disposed off in accordance with the guidelines for the disposal of electronic parts.

7 APPENDIX

7.1 List of Consumables

Article no.:	description	packing/unit
Calibration- and Rinsing solutions for COMBILINE BGA		
40 6 10 00 (3-4.100)	WASH 1 (Rinsing solution for BGA)	6x330 ml
40 6 10 20	BGA 1 (Calibration solution BGA low)	12x130 ml
40 6 10 30	BGA 2 (Calibration solution BGA high)	12x130 ml
for COMBILINE BGA+E		
40 6 10 10	WASH 2 (Rinsing solution for BGA plus E)	8x250 ml
40 6 10 40	BGA 3 (Calibration solution BGA plus E/low)	12x130 ml
40 6 10 50	BGA 4 (Calibration solution BGA plus E/high)	12x130 ml
40 6 10 45	CAL 3 (Calibration solution for ISE / low)	12x150 ml
40 6 10 55	CAL 4 (Calibration solution for ISE / high)	12x150 ml
for COMBILINE ISE		
40 6 10 15 (3-4.110)	WASH 2 (Rinsing solution for BGA plus E and ISE)	6x330 ml
40 6 10 60 (3-4.400)	CAL 3 (Calibration solution for ISE/low)	6x330 ml
40 6 10 65 (3-4.500)	CAL 4 (Calibration solution for ISE/high)	6x330 ml
for Combiline meta		
40 6 10 11	WASH 2+M (Rinsing solution for BGA plus E)	8x250 ml
40 6 10 40	BGA 3 (Calibration solution BGA plus E/low)	12x130 ml
40 6 10 50	BGA 4 (Calibration solution BGA plus E/high)	12x130 ml
40 6 10 45	CAL 3 (Calibration solution for BGA plus E/low)	12x150 ml
40 6 10 56	CAL 4+M (Calibration solution for BGA plus E/high)	12x150 ml
Special Solutions		
50 6 10 80	Protein remover	1 x 100 ml
50 6 10 84	Electrode cleaner	50 ml
50 6 10 88	Activating solution for pH-sensor	20 ml
Quality Controls		
Control Solutions for BGA		
50 6 20 10	Level I (acidosis)	30 ampoules
50 6 20 20	Level II (normal)	30 ampoules
50 6 20 30	Level III (alkalosis)	30 ampoules
Control Solutions for BGA plus E		
50 6 20 40	Level I (acidosis)	30 ampoules
50 6 20 50	Level II (normal)	30 ampoules
50 6 20 60	Level III (alkalosis)	30 ampoules
Control Solutions for BGA, ISE and metabolites		
50 6 20 45	Blood-Gas control + EGL Level (acidosis)	30 ampoules
50 6 20 55	Blood-Gas control + EGL Level II (normal)	30 ampoules
50 6 20 65	Blood-Gas control + EGL Level III (alkalosis)	30 ampoules

Data sheets about liquid content can be requested from manufacturer

Article no.:	description	packing/unit
Sampling Systems		
Capillaries		
50 6 30 08	hep. capillaries 8 cm/lg	250 pcs.
50 6 30 10	hep. capillaries 10 cm/lg	250 pcs.
50 6 30 12	hep. capillaries 12 cm /150µl	250 pcs.
Capillaries for instruments with Hb-sensor		
50 6 30 14	hep. capillaries 14 cm /175µl	250 pcs.
50 6 30 16	hep. capillaries 16 cm / 200µl	250pcs.
50 6 30 30	metal stirrers for capillaries	250 pcs.
50 6 30 35	magnet for stirrer	
50 6 30 40	end-caps for capillaries	500 pcs.
Aspiration Pipes		
3-7.200	pipe for control solution, activating solution etc.	10 pcs.
50 6 30 55	ampoule holder for aspiration pipe	1 pc.
Printer Paper		
50 6 50 00	printer paper	pack.=2 rolls
For sensor maintenance		
50 1 10 41	cleaning paste (silicon carbide)	1 box
50 1 10 45	cork with leather	1 pc.
50 1 10 50	pO_2 polishing kit	1 pc.

Data sheets about liquid content can be requested from manufacturer!

7.2 List of Spare Parts

Article no.:	description	packing/unit
Accessories for Maintenance		
60 6 40 00	service-set complete for combiline BGA, ISE, BGA+E	1 set
60 6 40 10	set tubings for roller-pump cl BGA, ISE, BGA+E	2 pcs.
60 6 40 01	service set complete for combiline meta	1 set
60 6 40 11	set tubings for roller-pump cl BGA, ISE, BGA+E	3 pcs.
40 6 40 15	tubing for magnetic valve VE1	1 pc.
40 6 40 20	tubing for magnetic valve VE2	1 pc.
40 6 40 25	tubing for magnetic valve ABS	1 pc.
3-8.106	sample port insert	1 pc.
40 6 40 40	filter for fan	1 pc.
40 6 40 45	moisture filter	1 pc.
Sensors		
pO_2-Sensor		
50 1 10 00	pO_2-Sensor complete	
50 1 10 10	pO_2-Sensor-unit with membrane shell	
50 1 10 15	gasket for Sensor-unit (8.0 x 1.0)	
50 1 10 20	pO_2-Sensor-casing with screw-cap	
50 1 10 21	screw cap for Sensor-casing	
50 1 10 25	gasket for Sensor-casing 1.8 x 1.0)	
50 1 10 30	pO_2-membrane shells	pack.= 5 pcs.
50 1 10 35	pO_2-fill solution	bot.=20 ml
pCO_2-Sensor		
50 1 20 00	pCO_2-Sensor complete	
50 1 20 10	pCO_2-Sensor-unit with membrane shell	
50 1 10 15	gasket for Sensor-unit (8.0 x 1.0)	
50 1 20 20	pCO2-Sensor-casing	
50 1 10 21	screw cap for Sensor-casing	
50 1 10 25	gasket for Sensor-casing 1.8 x 1.0)	
50 1 20 30	pCO_2-membrane shells	pack.=5 pcs.
50 1 20 35	pCO_2-fillsolution	bot.=20 ml
pH-Sensor		
50 1 30 00	pH-Sensor complete	
50 1 30 10	pH-Sensor-unit	
50 1 30 20	pH-Sensor-casing	
50 1 10 21	screw cap for Sensor-casing	
50 1 10 25	gasket for Sensor-casing 1.8 x 1.0)	
Hb-Sensor		
50 2 10 00	Hb-Sensor type II complete	
Lactate-Sensor		
50 4 10 00	Lactate -Biosensor, complete	1 pc
Glucose-Sensor		
50 4 20 00	Glucose-Biosensor, complete	1 pc

Data sheets about liquid content can be requested from manufacturer!

Article no.:	description	packing/unit
K^+-Sensor		
50 3 10 00	K^+-Sensor complete	
50 3 10 10	K^+-conducting system	
50 3 10 20	K^+-Sensor casing	
50 1 10 25	gasket for Sensor-casing 1.8 x 1.0)	
50 3 10 30	K^+-membrane shell with membrane	
50 3 10 35	K^+-fillsolution (organic tenside, buffer substances)	bot.=20 ml
Na^+-Sensor		
50 3 20 00	Na^+-Sensor complete	btl.= bottle
50 3 20 10	Na^+-conducting system	
50 3 20 15	gasket for conducting system (3.2 x 1.8)	
50 3 20 20	Na^+-Sensor-casing	
50 1 10 25	gasket for Sensor-casing 1.8 x 1.0)	
50 3 20 35	Na^+-fillsolution	bot.= 20 ml
Ca^{++}-Sensor		
50 3 30 00	Ca^{++}-Sensor complete	
50 3 30 10	Ca^{++}-conducting system	
50 3 30 20	Ca^{++}-Sensor casing	
50 1 10 25	gasket for Sensor-casing 1.8 x 1.0)	
50 3 30 30	Ca^{++}-membrane shell with membrane	
50 3 30 35	Ca^{++}- fillsolution	bot.=20 ml
Cl^--Sensor		
50 3 40 00	Cl^--Sensor complete	
50 3 40 10	Cl^-- conducting system	
50 3 40 20	Cl^--Sensor casing	
50 1 10 25	gasket for Sensor-casing 1.8 x 1.0)	
50 3 40 30	Cl^--membrane shell with membrane	
50 3 40 35	Cl^--fillsolution	bot.=20 ml
Li^+-Sensor		
50 3 50 00	Li^+-Sensor complete	
50 3 50 10	Li^+-conducting system	
50 3 50 20	Li^+-Sensor casing	
50 1 10 25	gasket for Sensor-casing 1.8 x 1.0)	
50 3 50 30	Li^+-membrane shell with membrane	
50 3 50 35	Li^+-fillsolution	bot.=20 ml
Reference-Sensor		
40 5 10 00	reference-sensor complete	
50 5 10 10	reference-conducting system	
50 3 20 15	gasket for conducting system (3.2 x 1.8)	
50 5 10 20	reference-Sensor casing	
50 1 10 25	gasket for Sensor-casing 1.8 x 1.0)	
40 5 10 50	reservoir for reference-Sensor casing	
50 5 10 30	ref.-membrane shell with membrane	
50 5 10 35	reference-fillsolution	bot.=20 ml
Sensor units (various)		
40 5 20 00	Sample Light Barrier Sensor (LB)	
50 1 10 25	gasket for Sensor-casing (O-ring 1.8 x 1.0)	
40 7 10 30	device for specimen input	
50 7 20 90	Temperature Sensor for temp. regulation (NTC)	

Data sheets about liquid content can be requested from manufacturer!

7.3 Specifications for Safety

The ESCHWEILER Combiline meets the following directives:

2004/108/EG	Electromagnetic Compatibility
2006/95/EG	Low voltage directive

Applied harmonised standards:

EN 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use: General requirements
EN 61010-2-08/A1	Safety requirements for electrical equipment for measurement, control, and laboratory use: Particular requirements for laboratory equipment for analysis
EN 61010-2-101	Safety requirements for electrical equipment for measurement, control, and laboratory use: Particular requirements for in vitro diagnostic (IVD) medical equipment
Emission:	
EN 55011 A2	Industrial, scientific and medical radio-frequency equipment – Emission: Class B
EN 61000-3-2	Harmonic current emissions
EN 61000-3-3	Voltage fluctuation and flicker
Immunity:	
EN 61326-1	Electrical equipment for measurement, control and laboratory use – EMC requirements: Industrial requirement
EN 61000-4-2	Electrostatic discharge immunity test
EN 61000-4-3 +A1	Radiated, radio-frequency electromagnetic field – immunity test
EN 61000-4-4	Electrical fast transient/burst immunity test
EN 61000-4-5	Surge immunity tests
EN 61000-4-6	Immunity to conducted disturbances, induced by radio frequency fields
EN 61000-4-11	Voltage dips, short interruptions and voltage variations immunity test

7.4 Declaration of Conformity

ESCHWEILER
automatic analysing systems

Eschweiler GmbH & Co. KG • Holzkoppelweg 35 • D - 24118 Kiel
phone: ..49-(0)431-546580
fax: ..49-(0)431-549423
e-mail: info@eschweiler-kiel.de
homepage: www.eschweiler-kiel.de

Declaration of EC-Conformity

as defined by **EC In-Vitro Diagnostica (IVD) directive 98/79/EG**

Eschweiler GmbH & Co. KG
Holzkoppelweg 35 / D-24118 Kiel / Germany

declares that the product

Description: blood gas-/ electrolyte- and metabolite - analysers

Model: **ESCHWEILER combi *line***

to which this declaration relates is in accordance with the provisions of the following directives

2004/108/EG	**Electromagnetic Compatibility**
2006/95/EG	**Low Voltage Directive**

Applied harmonised standards:

EN 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use: General requirements
EN 61010-2-08/A1	Safety requirements for electrical equipment for measurement, control, and laboratory use: Particular requirements for laboratory equipment for analysis
EN 61010-2-101	Safety requirements for electrical equipment for measurement, control, and laboratory use: Particular requirements for in vitro diagnostic (IVD) medical equipment
Emission:	
EN 55011 A2	Industrial, scientific and medical radio-frequency equipment – Emission: Class B
EN 61000-3-2	Harmonic current emissions
EN 61000-3-3	Voltage fluctuation and flicker
Immunity:	
EN 61326-1	Electrical equipment for measurement, control and laboratory use – EMC requirements: Industrial requirement
EN 61000-4-2	Electrostatic discharge immunity test
EN 61000-4-3 +A1	Radiated, radio-frequency electromagnetic field – immunity test
EN 61000-4-4	Electrical fast transient/burst immunity test
EN 61000-4-5	Surge immunity tests
EN 61000-4-6	Immunity to conducted disturbances, induced by radio frequency fields
EN 61000-4-11	Voltage dips, short interruptions and voltage variations immunity test

ESCHWEILER GmbH & Co. KG

Kiel, 01.04.2010

i.A Dr. H.-J. Heupke
(QCM)

Blutgas- und Elektrolytanalysatoren – in accordance with the guidelines of EN ISO 9001 EN ISO 13485 – ESCHWEILER QUALITY SYSTEM – in Übereinstimmung mit den Richtlinien der EN ISO 13485 EN ISO 9001 – blood gas- and electrolyte analysers

EC declaration combilineV2 IVD engl/01012010

7.5 Technical Specifications

Analyser type: fully-automated analyser for in-vitro-diagnostic of blood gas, electrolyte, Haemoglobin and Metabolites
Note: different according to the Combiline Types!

Processor: Z80 microcontroller

Sensors: pO_2, pCO_2, K^+, Ca^{++} Li^+, Na^+, Cl^-, pH, GLU, LAC, Ref.; Hb, (Sensors can be equipped differently according to the user's need)

Sensor array: Thermostated at 37.0 °C ± 0.1; backlighted for visual liquid control e.g. sediments, flow etc. inside the measuring capillary.
Two light barriers for liquid control
Warming up time: 1 hour

Sensor parameter	**range/unit**	**resolution**
pO_2	0 - 800 mmHg (SI-units selectable)	0.1
pCO_2	5 - 200 mmHg (SI-units selectable)	0.1
pH	6.000 - 8.000 pH	0.001
total-haemoglobin (tHb)	3 - 30 g/dl	0.1
barometric pressure	500 - 900 mmHg (SI-units selectable)	1.0
Na^+	20 - 250 mmol/l	1.0
K^+	0 - 20 mmol/l	0.1
Ca^{++}	0 - 5.00 mmol/l	0.01
Li^+	0.40 -5.00 mmol/l	0.01
Cl^-	20 - 250 mmol/l	1.0
GLU	0 - 30 mmol/l (0 - 550 mg/l)	0.1
LAC	0 - 20 mmol/l (0 - 180 mg/l)	0.1
Patient parameter to enter		
patient temperature	13 - 43 °C	0.1
haemoglobin (tHb)	0 - 30 g/dl (if not measured)	0.1
fraction of inspired O_2 (FIO2)	15 - 100 % only relevant for AaDO2	
respiratory quotient (RQ)	0.7 - 1.0 only relevant for AaDO2	
Calculated parameter		
actual bicarbonate (HCO3-A)	10 - 50 mmol/l	0.1
standard bicarbonate (HCO3-S)	10 - 50 mmol/l	0.1
base excess (BE)	-25 - 25 mmol/l	0.1
standard base excess (SBE)	-25 - 25 mmol/l	1.0
total CO_2 (TCO2)	10 - 50 mmol/l	0.1
buffer base (BB)	0 - 100 mmol/l	0.1
O_2 saturation of Hb (O2sat)	20 - 100%	0.1
O_2 content or concentr. (O2CT)	0 - 40%	0.1
pO_2 at 50% O2-sat. (P50)	10 - 50 mmol/l	0.01
alveolar to arterial oxygen-tension grade (AaDO2)	0 - 800 mmHg	0.1
haematocrit (Hct)	0 - 100% (only in combination with tHb)	0.1
hydrogen-ion concentration (H+)	10 - 1000 nmol/l	
Anion-Gap (AGAP)	0 - 99 mmol/l	0.1
Shunt (SHUNT)	0 - 50%	0.1
acid-base status	relevant diagnosis recorded on printer	

Valve array:	electrical control of liquids, backlighted for visual control of e. g. sediments, flow etc.
Sample Port:	Adapter for different capillaries and syringes; cleaned with Wash Solution automatically.
Pumps:	1 roller pump, (2 roller pumps in metabolite versions) 1 suction pump
Liquid control by:	Suction pump, roller pump, suction valve, ventilation-valve, vacuum vessel, moisture absorber.
System liquid:	combi*line* BGA: Wash 330 ml bottle,Waste bottle 330 ml equipped with a level Sensor. Calibration solution BGA 1 and BGA 2, 130 ml bag for pCO_2 and pH. combi*line* ISE: Wash 330 ml bottle,Waste bottle 330 ml equipped with a level Sensor. CAL3 and CAL4, 330 ml bottle for electrolytes. combi*line* BGA+E: Wash 250 ml bottle,Waste bottle 250 ml equipped with a level Sensor. Calibration solution BGA 3 and BGA 4, 130 ml bag for pCO_2 . CAL3 and CAL4, 130ml bottle for electrolytes. combi*line* meta: Wash 250 ml bottle,Waste bottle 250 ml equipped with a level Sensor. Calibration solution BGA 3 and BGA 4, 130 ml bag for pCO_2 . CAL3 and CAL4+M, 130ml bottle for electrolytes and metabolites.
Software:	loaded from EEPROM Software Languages available: English, German. Ask your representative for more information.
Dialogue:	LCD-display, illuminated, 15-lines, 30 characters each Keypad 0-9, ENTER-key, C: clear, ".": point 4 corresponding keys appealing to Software functions
Printer:	56 mm thermal-printer, for paper-rolls up to a diameter of 60mm
Interface:	RS 232
System time:	real time clock for date and time
Technical data of Power:	requirement: 70 W voltage: 115 - 230V / 50/60Hz fuses: 250V 2,5 A time lag Adapter with fuse compartment and noise filter and cold plug
Environment: conditions:	Rel. humidity: 30-90%, no condensation temperature +12 to +32 °C
Dimensions:	height 402 mm, width 325 mm, depth 432 mm
Weight approx.:	13 kg

Guarantee

The scope of the guarantee is determined by the laws in the country where the Combiline is purchased. If you have any questions about guarantee, please contact your authorised representatives. Your cash register receipt is a valid guarantee coupon.

7.6 Materials Provided with the combiline

Sensors:

1	pc	50 1 10 30	pO_2-membrane shell with membrane	
1	bot.	50 1 10 35	pO_2-fillsolution	20 ml
1	pc	50 1 20 30	pCO2-shell with Membrane	
1	bot.	50 1 20 35	pCO_2-fillsolution	20 ml
1	pc	50 5 10 30	Ref.-membrane shell with membrane	
1	bot.	50 5 10 35	Ref.-fillsolution	50 ml

depending on ordered type configuration:

1	pc	50 3 10 30	K^+ -membrane shell with membrane	
1	bot.	50 3 10 35	K^+ -fillsolution	20 ml
1	bot.	50 3 20 35	Na^+ - fillsolution	20 ml
1	pc	50 3 30 30	Ca^{++} - membrane shell with membrane	
1	bot.	50 3 30 35	Ca^{++} - fillsolution	20 ml
1	pc	50 3 50 30	Li^+ - membrane shell with membrane	
1	bot.	50 3 50 35	Li^+ - fillsolution	20 ml
1	pc	50 3 40 30	Cl- - membrane shell with membrane	
1	bot.	50 3 40 35	Cl- - fillsolution	20 ml

various accessories for Sensors:

1	pc	50 1 10 42	cork with leather	
1	box	50 1 10 41	cleaning paste (silicon carbide)	
1	pc	50 1 10 50	pO_2 polishing kit	
1	bot.	50 6 10 84	electrode cleaner	50 ml
5	pc		tape for closing of ventilation holes at membrane shells	
1	pc		exchange tool for sample light barrier capillary	
1	bot.	50 6 10 80	Proteinremover	100 ml

Reagents:

for Combiline BGA+E and BGA

2	bot.	40 6 10 11	WASH 2+M (Rinsing solution for BGA plus E)
2	bag	40 6 10 40	BGA 3 (Calibration solution BGA plus E/low)
2	bag	40 6 10 50	BGA 4 (Calibration solution BGA plus E/high)
2	bot.	40 6 10 45	CAL 3 (Calibration solution for BGA plus E/low)
2	bot.	40 6 10 56	CAL 4+M (Calibration solution for BGA plus E/high)

Quality controls:

1	pcl.		Blood Gas Control plus EGL - Evaluation Kit C-510 (for BGA, electrolytes and metabolites)

Gaskets

10	pc	50 1 10 25	o-ring for Sensor casing (all) 1.8 x 1.0

pc. = piece -- bot.= bottle -- Amp = Ampoule

Capillaries:

Capillaries for instruments without Hb-sensor

250	pc	50 6 30 08	hep. capillaries 8 cm/100µl (up to 4 parameter)
250	pc	50 6 30 10	hep. capillaries 10 cm/125µl (up to 6 parameter)
250	pc	50 6 30 12	hep. capillaries 12 cm/150µl (up to 8 parameter)

Capillaries for instruments with Hb-sensor

250	pc	50 6 30 12	hep. capillaries 12 cm/150µl (up to 4 parameter)
250	pc	50 6 30 14	hep. capillaries 14 cm/150µl (up to 7 parameter)
250	pc	50 6 30 15	hep. capillaries 16 cm/200µl (up to 11 parameter)
250	pc	50 6 30 30	metal stirrers for capillaries
1	pc	50 6 30 35	magnet for metal stirrers
500	pc	50 6 30 40	end caps for capillaries

various accessories:

2	rl	50 6 50 00	printer paper
1	set	40 6 40 00	maintenance set complete
5	pc.	3-7.200	aspiration pipe for control solution
1	pc.	50 6 60 55	ampoule holder for aspiration pipe
2	pc		syringe 2 ml
1	set		Fuses 2 x 2,5 A
1	pc.		mains cable
1	pc.		instruction manual

pc. = piece -- bot.= bottle -- pcl. = parcel -- rl = roll

7.7 Interface Description

Serial Interface RS 232

The transfer of data in the combi*line* program is performed with following parameter:
9600 Baud
8 data bit
1 start bit
1 stop bit
no parity bit
no handshake.
Data will be sent automatically after a sample or QC measurement only, at the time of printing in ASCII code.

7.8 Reference Literature

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Notices